

Exhibit 21

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE DISTRICT OF NEW JERSEY
3 CAMDEN VICINAGE

4 *****

5 IN RE: VALSARTAN, LOSARTAN, MDL No. 2875
6 AND IRBESARTAN PRODUCTS
7 LIABILITY LITIGATION Civil No.
8 19-2875
9 ***** (RBK/JS)

10 THIS DOCUMENT APPLIES TO ALL HON ROBERT B.
11 CASES KUGLER

12 *****

13 - CONFIDENTIAL INFORMATION -
14 SUBJECT TO PROTECTIVE ORDER

15 Continued Remote Videotaped via
16 Zoom Deposition of MIN LI, Ph.D., commencing at
17 7:08 a.m. China Standard Time, on the 22nd of
18 April, 2021, before Maureen O'Connor Pollard,
19 Registered Diplomat Reporter, Realtime
20 Systems Administrator, Certified Shorthand
21 Reporter.

22 - - -

23 GOLKOW LITIGATION SERVICES
24 877.370.3377 ph | 917.591.5672 fax
 deps@golkow.com

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1 APPEARANCES: ALL PARTIES APPEARED REMOTELY
2
3 MAZIE SLATER KATZ & FREEMAN, LLC
4 BY: ADAM SLATER, ESQ.
5 BY: CHERYLL A. CALDERON, ESQ.
6 BY: JULIA S. SLATER, ESQ.
7 BY: CHRISTOPHER GEDDIS, ESQ.
8 103 Eisenhower Parkway
9 Roseland, New Jersey 07068
10 973-228-9898
11 aslater@mazieslater.com
12 ccalderon@mazieslater.com
13 cgeddis@mazieslater.com
14 Representing the Plaintiffs

15 HOLLIS LAW FIRM
16 BY: IRIS SIMPSON, ESQ.
17 BY: C. BRETT VAUGHN, ESQ.
18 8101 College Boulevard, Suite 260
19 Overland Park, Kansas 66210
20 800-701-3672
21 iris@hollislawfirm.com
22 Representing the Plaintiffs

23 MORGAN & MORGAN
24 BY: STEPHANIE JACKSON, ESQ.
25 BY: HANNAH FUJIMAKI, ESQ.
26 20 North Orange Avenue, Suite 1600
27 Orlando, Florida 32801
28 sjackson@forthepeople.com
29 hfujimaki@forthepeople.com
30 Representing the Plaintiffs

31 FLEMING NOLAN JEZ, LLP
32 BY: DAVID HOBBS, ESQ.
33 2800 Post Oak Boulevard
34 Houston, Texas 77056
35 713-621-7944
36 david_hobbs@flaming-law.com
37 Representing the Plaintiffs

Page 507

1 APPEARANCES (Continued):
2
3 FARR LAW FIRM
4 BY: GEORGE T. WILLIAMSON, ESQ.
5 99 Nesbit Street
6 Punta Gorda, Florida 33950
7 941-639-1158
8 gwilliamson@farr.com
9 Representing the Plaintiffs

10 GREENBERG TRAUIG LLP
11 BY: KATE M. WITTLAKE, ESQ.
12 4 Embarcadero Center, Suite 3000
13 San Francisco, California 94111
14 415-655-1285
15 wittlakek@gtlaw.com
16 Representing the Defendants Teva
17 Pharmaceutical Industries, Ltd., Teva
18 Pharmaceuticals SA, Inc., Actavis LLC,
19 and Actavis Pharma, Inc.:

20 DUANE MORRIS, LLP
21 BY: NATHAN B. REEDER, ESQ.
22 30 South 17th Street
23 Philadelphia, Pennsylvania 19103
24 215-979-1164
25 nbreeder@duanemorris.com
26 Representing the Defendants Zhejiang
27 Huahai Pharmaceutical Co., Ltd.,
28 Princeton Pharmaceutical Inc., Huahai
29 U.S., Inc., and Solco Healthcare US,
30 LLC

Page 508

1 APPEARANCES (Continued):
2
3 DUANE MORRIS, LLP
4 BY: PATRICK C. GALLAGHER, ESQ.
5 1875 NW Corporate Boulevard
6 Boca Raton, Florida 33431
7 561-962-2131
8 pcgallagher@duanemorris.com
9 Representing the Defendants Zhejiang
10 Huahai Pharmaceutical Co., Ltd.,
11 Princeton Pharmaceutical Inc., Huahai
12 U.S., Inc., and Solco Healthcare US,
13 LLC

14 DUANE MORRIS, LLP
15 BY: FREDERICK R. BALL, ESQ.
16 100 High Street
17 Boston, Massachusetts 02110
18 857-488-4229
19 frball@duanemorris.com
20 Representing the Defendants Zhejiang
21 Huahai Pharmaceutical Co., Ltd.,
22 Princeton Pharmaceutical Inc., Huahai
23 U.S., Inc., and Solco Healthcare US,
24 LLC

25 CIPRIANI & WERNER, P.C.
26 BY: JULIA H. FERTEL, ESQ.
27 450 Sentry Parkway
28 Blue Bell, Pennsylvania 19422
29 610-567-0700
30 jfertel@c-wlaw.com
31 Representing the Defendant Aurobindo
32 Pharmaceuticals

Page 509

1 APPEARANCES (Continued):
2
3 PIETRAGALLO GORDON ALFANO BOSICK &
4 RASPANTI, LLP
5 BY: JOHN B. ZAPPONE, ESQ.
6 One Oxford Centre
7 Pittsburgh, Pennsylvania 15219
8 412-263-1840
9 jbz@pietragallos.com
10 Representing the Defendant Mylan
11 Pharmaceuticals, Inc.

12 Also Present: Phil Hughes
13 Andrew Huang, Esq.

14 Videographer: Judy Diaz

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<div> <div>Page 511</div> <div> <div>1 ZHP-320 Nonclinical Safety</div> <div>2 Assessment of</div> <div>3 N-nitrosodimethylamine</div> <div>4 (NMDA) and Recommended</div> <div>5 Limit in Drug Product,</div> <div>6 Bates CHARLESWANG000164</div> <div>7 through 182..... 649</div> <div>8 ZHP-321 Concise International</div> <div>9 Chemical Assessment</div> <div>10 Document 38 regarding NDMA.. 664</div> <div>11</div> <div>12 ZHP-315-t English translation of</div> <div>13 ZHP-315..... 514</div> <div>14</div> <div>15</div> <div>16</div> <div>17</div> <div>18</div> <div>19</div> <div>20</div> <div>21</div> <div>22</div> <div>23</div> <div>24</div> </div> </div>	<div> <div>Page 513</div> <div> <div>1 P R O C E E D I N G S</div> <div>2</div> <div>3 THE VIDEOGRAPHER: We're now on</div> <div>4 the record.</div> <div>5 My name is Judy Diaz. I am a</div> <div>6 legal videographer for Golkow</div> <div>7 Litigation Services.</div> <div>8 Today's date is April 22, 2021,</div> <div>9 and the time is 7:08 a.m.</div> <div>10 This remote video deposition is</div> <div>11 being held in the matter of Valsartan,</div> <div>12 Losartan, and Irbesartan Products</div> <div>13 Liability Litigation MDL.</div> <div>14 This is the continuation of the</div> <div>15 deponent Min Li Ph.D.</div> <div>16 All parties to this deposition</div> <div>17 are appearing remotely and have agreed</div> <div>18 to the witness being sworn in</div> <div>19 remotely.</div> <div>20 All counsel will be noted on</div> <div>21 the stenographic record.</div> <div>22 The court reporter is Maureen</div> <div>23 Pollard.</div> <div>24 ///</div> </div> </div>

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<p>1 MIN LI, Ph.D., 2 having been previously duly remotely sworn, 3 was examined and testified further as 4 follows: 5 6 MR. SLATER: Cheryll, I think 7 we can put up Exhibit 315, the next 8 exhibit, and I think there's an 9 English translation you can put in the 10 box for counsel. 11 (Whereupon, Exhibit Numbers 12 ZHP-315 and ZHP-315-t were marked for 13 identification.) 14 MR. SLATER: Is it possible to 15 make that a little smaller? Let's get 16 that so we can see it. 17 FURTHER EXAMINATION 18 BY MR. SLATER: 19 Q. In front of us we have 20 Exhibit 315, which is a July 22, 2018, 21 e-mail. 22 And if we could, let's look, 23 first of all, just at who it's written from 24 and to. Can you just let us know what that</p>	<p>1 to the e-mail, by somebody who also worked at 2 SynCores, correct? 3 A. Yes, looks like, yeah. 4 Q. And tell us, let's start with 5 the introduction part, what that says. 6 A. He said, "Dr. Huang, updated 7 the data as shown below." It said, starting 8 from the number 6, like big points, or he 9 said that, you know, you can look from the 10 number 6, which is the major, you know, 11 points, like they have like, you know, one, 12 two, three, you know, like a big points, 13 right. So number 6. 14 Q. Before you read 6, I just 15 wanted to establish, so -- rephrase. 16 So this e-mail was written to 17 Mr. Huang, and it says that an updated table 18 is shown, and he's starting from heading 19 number 6, it looks like, right? 20 A. Yes, exactly, yep. 21 Q. Let's look at -- first, it says 22 in the first one, I see a 111.4 ppm. What is 23 that referring to? 24 A. Just basic, you know, you know,</p>
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<p>1 says, please, in terms of who it's written 2 from and to? 3 A. I don't know this person 4 X.W. Guo. But I certainly know they're 5 recipients, Chinese name Huang Luning, he is 6 the vice president at SynCores. 7 Q. I missed who you said. Who was 8 the person who received it? 9 A. Huang Luning. 10 Q. And he's the head of SynCores? 11 A. No, he is the vice president of 12 SynCores. 13 Q. The vice president of SynCores. 14 So this e-mail was sent from 15 the vice president of Shanghai SynCores -- 16 A. No, I'm sorry. I don't know 17 who the sender is, okay. That's, you know, 18 you know, you know, like Guo, I don't know 19 who this person. But the recipient I know. 20 I personally know him, yes. 21 Q. So the recipient is the vice 22 president of SynCores. 23 A. Yes. 24 Q. And it was written, according</p>	<p>1 what is written here, right. So first, you 2 know, three characters is basically the 3 Chinese name for valsartan. We call it 4 (Chinese pronunciation valsartan), right? 5 So there's a parentheses, 111.4 6 ppm, and the next thing he said, you know, 7 genotoxic, probably, you know, means NDMA. 8 Okay. 9 So my guess is, okay, just 10 based upon, you know, you know, what I can 11 look at here, he probably referred to a 12 particular valsartan batch which has NDMA, 13 you know, in terms of its contents, like an 14 111.4 ppm. 15 Q. I wanted to see if we could go 16 through and just understand how we calculate 17 something. And maybe you can help me. I 18 want to try to convert ppm to nanograms. 19 So if we have 111.4 ppm, my 20 understanding is that we would then need to 21 know the milligrams of the pill as part of 22 the calculation, is that correct? 23 A. Yeah, you can certainly 24 calculate based upon 111.4, yeah.</p>

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1 Q. So it was a 320-milligram
2 valsartan pill and it was 111.4 ppm, would we
3 just multiply 111.4 times 320 to find the
4 nanograms?
5 A. This would be in the unit also
6 of the milligram, right? So, yeah, so 320
7 times 111.4, you will get -- you have to
8 divide it by 1 million, right, divide it by 1
9 million, and then the number you got should
10 be in the unit of milligram.
11 Q. Well, it's my understanding
12 there's 1 million nanograms in a milligram,
13 is that correct?
14 A. Well, ppm basically means 1
15 particle per million. It doesn't matter,
16 like, yeah, what the -- you know, you know,
17 it's a ratio.
18 Q. So if it's -- rephrase.
19 If it's measured in parts per
20 million --
21 A. Right. So, yeah, basically if
22 you wanted to know, you know, equivalent to
23 320 milligram a tablet, right, made from
24 dispatch, so I think the calculation would be

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1 320 times 111.4 divided by 1 million.
2 And then you've got, you know,
3 like, whatever the XYZ number, right, but the
4 unit will be milligram, because you're
5 starting from 320 milligram.
6 Q. Well, I'm trying to calculate
7 in nanograms.
8 A. Nanograms, then you will be --
9 let's see. You will be nanograms, so
10 milligram, micro- -- yeah, so there you will
11 be -- let me see. You will be -- I think
12 then you will be times 1 million again,
13 right? So --
14 Q. So it would just be --
15 A. Yeah. Yeah. Yeah. So
16 basically they just cancel out, then, right.
17 Q. So to find out how many
18 nanograms this would be if it was a
19 320-milligram pill, we would multiply 111.4
20 times 320 to find out how many nanograms,
21 correct?
22 MR. GALLAGHER: I'm going to
23 object to this line of questioning
24 because it's calling for expert

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1 testimony.
2 Look, it's not a math test. If
3 you want to ask about facts and stuff,
4 but asking him how to calculate
5 stuff --
6 You can answer, Dr. Li. You
7 should answer, to the extent you know
8 and can.
9 BY MR. SLATER:
10 Q. Dr. Li, just because this way
11 we'll have a basis when we ask questions
12 later and we'll know our vocabulary, if I
13 multiply 111.4 ppm times 320 milligram,
14 assuming it was a 320-milligram pill, I come
15 up with 35,648 nanograms.
16 That would be a correct
17 calculation, correct?
18 A. I'm sorry, what is the number
19 again that you calculated?
20 Q. Sure.
21 111.4 parts per million times
22 320 milligrams comes to 35,648 nanograms.
23 MR. GALLAGHER: Again, I'm
24 going to object to this as calling for

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1 expert testimony. It's not a math
2 test.
3 MR. SLATER: I think Dr. Li has
4 a grasp on the calculation, so I'm not
5 really sure what the objection is.
6 And this falls -- it helps us
7 to answer some of the questions and
8 the topics as we go forward.
9 A. It looks like so, yeah, mm-hmm.
10 BY MR. SLATER:
11 Q. Okay. So just to have a clean
12 question and answer, the reference --
13 rephrase.
14 The reference to 111.4 ppm, if
15 we were to assume that was in a 320-milligram
16 valsartan pill, we would multiply 111.4 times
17 320 to find out how many nanograms, and here
18 that would be 35,648, correct?
19 MR. GALLAGHER: Same objection.
20 A. Yeah, looks like so, mm-hmm.
21 MR. SLATER: Okay. Let's
22 scroll down now, Cheryll, to the next
23 part. Perfect.
24 BY MR. SLATER:

<p>Page 522</p> <p>1 Q. Looking now at Section 7, let's 2 walk through that. It's my understanding it 3 refers to a DMF blank experiment. 4 What does that mean, "a DMF 5 blank experiment"? 6 A. I don't know. I mean, this is 7 SynCores experiment. So let me read through. 8 I will try to see whether I can have some 9 understanding. DMF... 10 (Witness reviewing document.) 11 A. Okay. So I think, yeah, it 12 looks like they just treated the DMF with 13 sodium nitrite, and also like in the presence 14 either acid or base, it looks like. Yeah, 15 that's what -- you know, they're trying to 16 understand how NDMA would be formed from, you 17 know, DMF. Yeah, basically it's sort of like 18 a part of a mechanistic study, yeah. 19 Q. If I understand correctly -- 20 rephrase. 21 If I understand correctly, 22 SynCores was studying the origin of how the 23 NDMA was formed as part of a root cause 24 investigation, correct?</p> <p>Page 523</p> <p>1 A. Looks like, yes. 2 MR. GALLAGHER: Objection. 3 Lacks foundation. 4 BY MR. SLATER: 5 Q. If I understand this correctly, 6 they indicated that as long as sodium nitrite 7 is added, genotoxic impurities will be 8 generated, is that correct? 9 A. The statement says so. And I 10 think, you know, the genotoxic impurity here 11 looks like, you know, from the context 12 specific, was specifically referring to NDMA. 13 Q. And I think they then said -- 14 rephrase. 15 And it then refers to 16 generating this NDMA is extremely obvious in 17 an acidic environment, is that correct? 18 A. Let me -- let me double-check. 19 Yes, looks like so. Acidic, 20 yes, it's quite obvious, yes, was a ppm. 21 Q. They refer to the fact that 22 this is caused by the additional reaction of 23 dimethylamine. That is a degradant of DMF, 24 correct?</p>	<p>Page 524</p> <p>1 A. Yeah, the next sentence it said 2 it should be DMF decomposition becoming 3 dimethylamine and then reacted with sodium 4 nitrite under condition, yes. 5 Q. And I think they conclude that 6 the purpose of the experiment had been 7 achieved, and that they can't explain that 8 NDMA is only derived from dimethylamine in 9 DMF because you need the sodium nitrite as 10 stated above to create the NDMA. 11 Do I understand that correctly? 12 MR. GALLAGHER: Objection. 13 Vague, and lacks foundation. 14 You can answer, Dr. Li. 15 A. Okay. I think -- I think the 16 conclusion says NDMA formation, it will not 17 only originate from the methylamine that's 18 originally present in DMF. So based -- based 19 upon, you know, what it says, right, from 20 everything written here, it -- so my 21 understanding is like under the acidic 22 condition DMF, you know, would form -- I'm 23 sorry, DMF would decompose to give 24 dimethylamine.</p> <p>Page 525</p> <p>1 So at least, you know, from 2 this experiment it seems like, you know, 3 there -- NDMA would from, you know, two 4 sources, right, or from two parts of the 5 dimethylamine. 6 So one part of the 7 dimethylamine would be originally present, 8 and the other part of the dimethylamine would 9 be, you know, decomposition product under the 10 acidic condition, you know, or under that 11 particular experimental condition they was 12 performing. 13 BY MR. SLATER: 14 Q. And I think they had said -- 15 rephrase. 16 They had stated above that the 17 NDMA will be created as long as sodium 18 nitrite is added. 19 Do I understand that correctly? 20 A. The first, the very -- after 21 the column, right, yeah, the first sentence 22 says, yeah, like as long as you adding sodium 23 nitrite, yeah, it will generate NDMA. 24 And then the next sentence</p>
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<p style="text-align: right;">Page 526</p> <p>1 says, under acidic condition it will be much 2 more obvious, yeah, like a breakdown with 3 ppm. 4 And then the next one says it 5 should be DMF, you know, decomposition. 6 So for everything here, it 7 looks like, you know, the majority of the 8 NDMA, all the dimethylamine, you know, to be 9 converted into, you know, NDMA would be from 10 the decomposition of DMF. 11 Q. Combined with the sodium 12 nitrite? 13 A. Combined with sodium nitrite, 14 yeah, under acidic conditions. 15 Q. And you talked yesterday about 16 the concept of connecting the dots. This 17 would be an example of people connecting the 18 dots. Is that fair? 19 A. It is fair, but this is 20 after -- 21 MR. GALLAGHER: Objection. 22 A. Sorry. But this is, you know, 23 after, you know, this event came out and they 24 tried to understand, yeah, exactly what would</p>	<p style="text-align: right;">Page 528</p> <p>1 know, previously, you know, the whole 2 industry as well as, you know, the regulator, 3 you know, all, you know, had this knowledge 4 gap, obviously including ZHP. 5 MR. SLATER: Let's take that 6 document down and go to Exhibit 212, 7 please. If we could, Cheryll, let's 8 go to page -- the Bates number 1308 in 9 the bottom right, the last three 10 digits. 11 Actually let's stop for a 12 second. Don't go anywhere. I'll just 13 identify the document first. 14 Q. We have on the screen 15 Exhibit 212, which is a report, and the topic 16 title is "Investigation regarding an unknown 17 impurity," and then in parentheses "Genotoxic 18 Impurity" with regard to valsartan. 19 Do you see that? 20 A. Mm-hmm. 21 Q. Okay. 22 MR. SLATER: Let's go now to 23 page -- the page that has the 308 as 24 the last three digits, please.</p>
<p style="text-align: right;">Page 527</p> <p>1 happen. 2 BY MR. SLATER: 3 Q. And as part of the analysis 4 that ZHP performed in looking back as to why 5 this happened, it was understood that this 6 was not recognized when the process was being 7 created to use zinc chloride due to 8 insufficient study and insufficient research, 9 correct? 10 MR. GALLAGHER: Objection. 11 Vague, calls for speculation. 12 BY MR. SLATER: 13 Q. I'll ask it again. Let me ask 14 a new question, because counsel said that I 15 asked a question that was vague and called 16 for speculation so I want to try to fix it. 17 ZHP in 2018, in looking back, 18 concluded that the reason this was not 19 figured out and these dots were not connected 20 back in 2011 was because of insufficient 21 research and insufficient study, correct? 22 MR. GALLAGHER: Objection. 23 Vague. 24 A. As I already answered, you</p>	<p style="text-align: right;">Page 529</p> <p>1 A. One thing, you know, but just 2 by looking at this document it looks like 3 this is only a draft. We have -- I think 4 have a final, finalized, you know, signed 5 document. So I don't know, should we look at 6 the final document? 7 Q. No, we'll look at this 8 document. 9 MR. SLATER: Scroll down a 10 little further, Cheryll, so we get the 11 bottom half of the page, please. 12 Perfect. 13 Q. Section 5.2 is titled "Control 14 strategy." 15 Do you see that? 16 A. Mm-hmm. 17 Q. Under the heading of 5.2, 18 "Control strategy," it says, "Due to 19 insufficient extent and depth of process 20 research at the early stage, as well as 21 insufficient study and understanding of 22 potential genotoxic impurities, only side 23 reaction product and degradation products 24 were studied, and was unaware of the further</p>

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1 reaction between degradation products and raw
2 material."
3 Do you see what I just read?
4 A. Mm-hmm.
5 Q. So certainly as of the time
6 this document was drafted, the conclusion at
7 that time was that there was insufficient
8 extent and depth of process research as well
9 as insufficient study and understanding of
10 potential genotoxic impurities. That's what
11 the document states, correct?
12 MR. GALLAGHER: Object to the
13 questions on this document to the
14 extent the witness said this is not a
15 final version and asked to see the
16 final version.
17 But, Dr. Li, you should answer,
18 if you can answer.
19 A. I mean, yeah, based upon this
20 version, you know, this is what it says. But
21 as I said, you know, this statement is still
22 consistent, you know, with the fact, you
23 know, that I already said that, you know, the
24 whole industry as well as, you know, ZHP and

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1 also the regulators, you know, everybody had
2 the same knowledge gap at the time.
3 MR. SLATER: Take that document
4 down, please.
5 BY MR. SLATER:
6 Q. Who is Charles Wang?
7 A. Charles Wang, who is a
8 toxicologist, you know, who is the consultant
9 of Huahai or ZHP.
10 Q. Was he somebody that was an
11 independent consultant, had his own company?
12 A. Sort of, yeah.
13 Q. What do you mean "sort of"?
14 A. He was doing, you know, that --
15 you know, he is a long-time friend, and so,
16 you know, you know, he is a trained
17 toxicologist, so when we had a -- you know,
18 you know, this issue, you know, when this
19 issue came out we came to him, you know, for
20 help.
21 Q. I asked you if he had an
22 independent consulting company. Did he have
23 an independent consulting company?
24 A. That I don't know. I mean, you

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1 know, whether he set up -- you know, I don't
2 know. I had no details about this.
3 Q. You said he was a long-time
4 friend. Who was he a long-time friend of?
5 A. Myself.
6 Q. How did you know him?
7 A. We know him because, you know,
8 he and I, we both have been the member of a
9 professional, you know, association, it's
10 called Sino-American Pharmaceutical
11 Association, and he and I, you know, were
12 both, you know, like a member, like long-time
13 members. This is a nonprofit, you know,
14 professional organizations started in New
15 Jersey, I think around time of 1993.
16 Q. Did you ever work together?
17 A. No, we never worked together.
18 Q. And by the way, I think I
19 forgot to ask you the other day, there's
20 someone at ZHP named Eric, and if I don't
21 pronounce his name correctly, let me -- Eric
22 Tsai, T-S-A-I?
23 A. Eric Tsai, yeah.
24 Q. Did you work with him in the

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1 past before you came to ZHP?
2 A. We actually worked in the same
3 company, but we were not in the same
4 department. Yeah.
5 Q. What company did you work at
6 with Eric Tsai?
7 A. Merck & Company. When I first
8 joined Merck & Company in 1998, Eric Tsai, he
9 was already there. Yeah. And I left Merck
10 the first time in 2005, as far as I remember,
11 he still was, you know, with Merck. Yeah.
12 Q. Was it just a coincidence that
13 the two of you ended up at ZHP, or was there
14 some connection there?
15 A. Perfectly coincidental.
16 Q. Coming back to Charles Wang,
17 you said he was a long-time friend. When did
18 you meet him?
19 MR. GALLAGHER: Adam, are we
20 moving on from the 30(b)(6) to
21 individual?
22 MR. SLATER: No, we're not.
23 MR. GALLAGHER: I'm going to
24 object to all this as outside the

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1 scope of the 30(b)(6).
 2 MR. SLATER: I'm confident that
 3 it's within the scope. I'm confident
 4 that I'm allowed to ask who he was,
 5 because you know who he is, so I don't
 6 think you should have an issue with me
 7 asking the questions.
 8 MR. GALLAGHER: I don't have a
 9 problem with you asking the questions.
 10 It's just that it's outside the scope
 11 of the 30(b)(6).
 12 MR. SLATER: We disagree.
 13 So I'm going to continue now,
 14 okay?
 15 MR. GALLAGHER: Absolutely.
 16 It's outside the scope of the
 17 30(b)(6), but Dr. Li should answer to
 18 the extent he knows personally.
 19 BY MR. SLATER:
 20 Q. So I'll ask the question again,
 21 Doctor.
 22 A. It's such a long time, you
 23 know.
 24 Q. Let me ask the question again.

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1 I don't mean to interrupt you, but let me
 2 just ask the question.
 3 A. Okay. Sure.
 4 Q. How long -- well, rephrase.
 5 When did you meet Charles Wang?
 6 MR. GALLAGHER: Objection.
 7 Outside the scope.
 8 A. You know, there's such a long
 9 time, so I don't remember exactly which year.
 10 I would say somewhere, you know, like --
 11 probably I would say in late, you know, '90s,
 12 or maybe early 2000. You know, like late
 13 1990s, somewhere around that period.
 14 BY MR. SLATER:
 15 Q. When you said he was a
 16 long-time friend, I might have misheard. I
 17 thought maybe that you said "of us," or in
 18 plural. So was it with somebody else at ZHP?
 19 MR. GALLAGHER: Objection.
 20 Outside the scope.
 21 You can answer.
 22 THE WITNESS: Yeah, sorry.
 23 I don't know, you know, who
 24 else, you know, you know, he himself

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1 considered to be a long-time friend.
 2 I really don't know. I cannot speak
 3 for him, okay.
 4 BY MR. SLATER:
 5 Q. Did he know anyone else at ZHP,
 6 to your knowledge?
 7 A. Oh, yes.
 8 MR. GALLAGHER: Objection.
 9 Outside the scope.
 10 THE WITNESS: Sorry.
 11 BY MR. SLATER:
 12 Q. Who?
 13 MR. GALLAGHER: Objection.
 14 Outside the scope.
 15 BY MR. SLATER:
 16 Q. Who else did he know at ZHP, to
 17 your knowledge?
 18 MR. GALLAGHER: Objection.
 19 Outside the scope.
 20 A. I mean, based upon my personal
 21 knowledge, you know, he knows Mr. Jun Du.
 22 BY MR. SLATER:
 23 Q. Do you have any idea how they
 24 knew each other?

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1 MR. GALLAGHER: Objection.
 2 Outside the scope.
 3 A. As far as I understand, they
 4 probably -- okay, that's just my guess. They
 5 probably, you know, essentially, you know,
 6 you know, came to know each other.
 7 Also through the same
 8 organization, you know, because, you know,
 9 this organization, you know, that I just
 10 mentioned, it's scientific, you know, you
 11 know, oriented. And so every year, you know,
 12 this organization will be, you know, you
 13 know, holding like conferences, scientific
 14 conferences, you know, you know, career, like
 15 a workshop, you know, things like that.
 16 And Huahai US, you know, at
 17 least for a period of time, you know, was
 18 the -- you know, the sponsor of some of the
 19 meeting events.
 20 MR. SLATER: Let's put up our
 21 next exhibit. We'll call it Number
 22 316. It's CHARLESWANG000289.
 23 (Whereupon, Exhibit Number
 24 ZHP-316 was marked for

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1 identification.)
2 MR. SLATER: Let's go to the
3 beginning of the e-mail chain on the
4 second page, please.
5 I want to get the e-mail --
6 yeah. Can you, Cheryll, possibly
7 scroll up so we can get the -- no, the
8 other way. There you go. Stop.
9 Perfect.
10 BY MR. SLATER:
11 Q. Looking now at the second page
12 of this e-mail chain where the Bates number
13 is CHARLESWANG000290.
14 Do you see that?
15 A. 000290. Where is the --
16 Q. It's probably behind the
17 pictures of people.
18 A. Oh, let me see. Sorry. Okay.
19 Oh, yeah, mm-hmm.
20 Q. Looking at this e-mail chain,
21 starting with the first e-mail in the chain,
22 which starts at the bottom of the second
23 page, it's an e-mail from yourself, Min Li,
24 to Charles Wang, June 6, 2018.

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1 And you say you're
2 forwarding -- or subject says "Forward: WHO
3 Report," and you say, "Please see the
4 report."
5 A. Can I see that? I'm sorry.
6 Can I see that word?
7 Q. I'm just asking, do you see
8 what I just read, the June 6, 2018 date?
9 A. Yeah, I see the date, but I
10 don't see any content.
11 Q. That's the e-mail that we were
12 provided, so I'll ask the next question.
13 June 6, 2018 is the day after
14 Novartis confirmed to your company that they
15 had identified the NDMA in the valsartan they
16 were testing through the outside lab,
17 Solvias.
18 We went through that yesterday,
19 right?
20 A. That was -- as I said, we
21 received the e-mail, you know, you know, they
22 indicated they suspect, you know, that that
23 was the NDMA.
24 Q. And this is the -- rephrase.

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1 This is the next day, June 6th,
2 correct?
3 A. Yes.
4 Q. You say in this e-mail, "Please
5 see the report." I assume you had spoken
6 with Charles Wang before you sent this
7 e-mail.
8 Do you recall?
9 A. I do not recall.
10 Could I just see, you know, you
11 know, that particular content that you just,
12 you know, reading twice already?
13 Q. I'm reading literally what's
14 right in front of you, sir.
15 A. Oh, "Please see the report."
16 Yeah. Yeah.
17 Q. It looks like you had written
18 to Charles Wang from Yahoo Mail on Android.
19 Do you see that?
20 A. Yes, mm-hmm.
21 Q. What's an Android?
22 A. What's Android? That was my,
23 you know, US, you know, cell phone, you know,
24 you know, at that time, it looks like.

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1 Q. Do you know who the
2 manufacturer is of the Android?
3 A. I don't remember. It could
4 be -- let's see. It could be a Samsung, you
5 know, smartphone, but I really don't remember
6 exactly.
7 Q. Was that phone turned in to be
8 checked to produce documents to us as part of
9 the production obligations in this
10 litigation?
11 A. That phone has been dead, I
12 think. Yeah, that phone -- so I think I, you
13 know, changed to my current phone. That
14 phone has been -- yeah.
15 Q. That phone is dead?
16 A. Yeah.
17 Q. Is it buried? Is it buried, or
18 is it still available?
19 A. No, it's no longer available.
20 It has been disposed, you know, because it's
21 no longer usable, totally unusable.
22 Q. We know it was working on
23 June 6, because we see the e-mail that you
24 sent from your Android, right?

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1 A. Yes.
 2 Q. June 6, 2018 it was working,
 3 right?
 4 A. Oh, yeah, uh-huh.
 5 Q. When did it stop working?
 6 A. When did it stop working.
 7 Sometime after -- I don't -- see, I don't
 8 remember exactly. It -- let me see. I just
 9 don't remember, you know, you know, all of
 10 these details.
 11 Q. Did that phone die in 2018 or
 12 2019?
 13 A. I just --
 14 MR. GALLAGHER: Objection.
 15 THE WITNESS: Sorry, go ahead.
 16 MR. GALLAGHER: Objection.
 17 Asked and answered.
 18 You can answer, Dr. Li.
 19 A. Yeah. I just don't remember
 20 right now. I mean...
 21 BY MR. SLATER:
 22 Q. Did you pay for that phone, or
 23 did your company pay for it?
 24 A. I paid for that phone myself.

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1 Q. When you replaced that phone,
 2 did you do that yourself, or did the company
 3 have any part of you replacing the phone?
 4 A. Everything, you know, I did
 5 myself, like I paid for myself.
 6 Q. The phone that you replaced
 7 this Android with is what, what type of
 8 phone?
 9 A. It should be, you know, this
 10 new Samsung phone that I'm using right now.
 11 Q. Do you know what type of phone
 12 it is?
 13 A. What type of this phone. At
 14 the time that I bought it should be kind of
 15 like a top of the line, you know, you know,
 16 Samsung phone, but I don't remember exactly,
 17 you know, the model.
 18 Q. Is it in the room with you
 19 right now?
 20 A. Yeah, it is in this room, yeah.
 21 I can take a look if you want.
 22 Q. Can you take a look right now
 23 and tell me what kind of phone it is?
 24 A. Sure.

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1 Oh, let me see, it's probably
 2 from the setting, right, looking about the
 3 phone. Okay. It's model number SM-N950U.
 4 Q. Is it an Android, is it a
 5 model -- is that the model?
 6 A. Yeah, it should be Android
 7 operating, yeah. Everybody else, yeah, I
 8 think other than -- other than the, like,
 9 Apple, right.
 10 Q. When you bought this new phone,
 11 did you get some sort of a warranty or some
 12 sort of protection plan where if something
 13 happened to it you could use that to help fix
 14 it?
 15 A. No.
 16 MR. GALLAGHER: I'm going to
 17 object to this line as outside the
 18 scope as well.
 19 But please go ahead.
 20 A. Yeah, I think we usually don't
 21 buy those protection plans.
 22 BY MR. SLATER:
 23 Q. What would you need to do to
 24 tell me the day that you got the new phone so

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1 we'd know when you replaced the old phone?
 2 MR. GALLAGHER: Objection.
 3 Asked and answered.
 4 A. I really need to, you know, dig
 5 into some of the detail if I, you know, if I,
 6 you know, you know, have to tell you exactly
 7 the -- I need to -- I need to do some
 8 research.
 9 BY MR. SLATER:
 10 Q. Sometimes the Samsung phones
 11 have the name on the back of the phone. Can
 12 you look at the back of your phone and see
 13 what type you have now?
 14 A. The name of the phone. On the
 15 back cover of my phone? Let me see. I need
 16 to remove the protection. Hold. Galaxy
 17 Note 8, yeah.
 18 Q. You said Galaxy Note 8?
 19 A. Yes.
 20 Q. Was your Galaxy Note 8 phone
 21 provided to your company for documents and
 22 information to be provided to us as part of
 23 this litigation?
 24 A. No. Because, you know, once I

<p style="text-align: right;">Page 546</p> <p>1 got this Galaxy phone, you know, it's -- I 2 don't think it's been used with this 3 communication. 4 Q. Where did you get the phone? 5 Did you buy it at a store? 6 A. Yeah, I buy it in the store, 7 yes. 8 Q. What store did you buy it at? 9 MR. GALLAGHER: I'm going to 10 object to this entire line as outside 11 the scope and, you know, bearing 12 into -- 13 MR. SLATER: Well, I'll ask you 14 a question, Counsel, maybe it will 15 move things along. 16 Can you represent right now 17 that Dr. Li's phones were both 18 properly collected and reviewed to 19 make productions of documents and 20 information to us pursuant to the 21 discovery obligations in this 22 litigation? 23 MR. GALLAGHER: I can represent 24 that we collected from all the devices</p>	<p style="text-align: right;">Page 548</p> <p>1 objecting outside the cope and veering 2 into wildly irrelevant. 3 BY MR. SLATER: 4 Q. While we're on it, I had asked 5 you on the first night of the deposition when 6 you were first told about the deposition, and 7 you said it was by an e-mail about six months 8 ago, and I asked if you would check that 9 date. Did you do so? 10 A. I'm sorry, check what? 11 Q. The date of the e-mail that you 12 received the first time you were told you 13 were going to be deposed in this litigation. 14 MR. GALLAGHER: Object as 15 calling for speculation, and to the 16 extent it calls for attorney/client 17 privileged information. 18 And to the extent you know and 19 can answer without disclosing 20 information regarding communications 21 with your attorneys, you can. But to 22 the extent it would disclose 23 information communicated from 24 attorneys for ZHP, I instruct you not</p>
<p style="text-align: right;">Page 547</p> <p>1 that we needed to collect from to get 2 the documents to meet our discovery 3 obligations. 4 MR. SLATER: Does that include 5 the phone he was using on -- rephrase. 6 Does that include the phone 7 that was being used on June 6, 2018? 8 MR. GALLAGHER: I think he told 9 you that phone is -- no longer exists. 10 MR. SLATER: Well, I'm asking 11 you because we're asking these 12 questions so we can match up the dates 13 and find out when the phone "died" and 14 we're going to track that phone. 15 MR. GALLAGHER: If you want 16 to -- if you want to continue, I'm 17 just objecting as outside the scope 18 and, you know, veering in wildly 19 irrelevant. 20 If you want to, you know, 21 submit a request in writing for us to 22 look at something, we're happy to do 23 that. But you're welcome to do your 24 deposition as you'd like. I'm just</p>	<p style="text-align: right;">Page 549</p> <p>1 to answer. 2 A. So -- so I -- you know, well, 3 first of all, I haven't had a chance, you 4 know, you know, you know, to do that. But I 5 guess after, you know, after this deposition, 6 you know, I can take some effort, you know, 7 to look it up. 8 But, you know, these past few 9 days, you know, I have been very exhausted, 10 and I also need to, you know, read through 11 some of the, you know, documentation, you 12 know, right, to -- for continuous prepare, 13 you know, for this deposition, so I really 14 haven't done, you know, this information 15 search. 16 BY MR. SLATER: 17 Q. You told me on -- rephrase. 18 You told me that it would have 19 been an e-mail from Maggie Kong, so you could 20 just search your e-mails for her name and 21 see -- 22 A. No, I said that -- 23 MR. GALLAGHER: Let me -- slow 24 down. Sorry.</p>

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1 Again, I'm going to object to
 2 the extent you're asking him to
 3 speculate, and to the extent it calls
 4 for attorney/client privileged
 5 information.
 6 Adam, if you want to send us a
 7 request we can -- in writing, we can
 8 go back and look, and to the extent
 9 that it doesn't involve
 10 attorney/client information we can
 11 share that.
 12 A. I think, yeah, I think, I think
 13 my counsel will provide an accurate, you
 14 know, dates, yeah.
 15 BY MR. SLATER:
 16 Q. We also talked the other day
 17 about when your Lenovo ThinkPad broke and you
 18 replaced it. Did you look into what the date
 19 was when that happened?
 20 A. That --
 21 MR. GALLAGHER: Same objection.
 22 BY MR. SLATER:
 23 Q. Lenovo ThinkPad, I'm sorry.
 24 A. That, as I said, that probably,

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1 let's see, I think it's -- it's probably
 2 somewhere around May 2018.
 3 But again, you know, you know,
 4 I need to go back, you know, to talk to, you
 5 know, my IT people, you know, to see what
 6 exactly date, you know, they provided, you
 7 know, this current one, you know, to me.
 8 MR. GALLAGHER: And, again,
 9 Adam, same objections. And if you
 10 want to send us a request in writing,
 11 we can take that under advisement.
 12 BY MR. SLATER:
 13 Q. Why did you contact Charles
 14 Wang -- well, rephrase. Let me ask you this.
 15 Did you contact Charles Wang as
 16 a result of Novartis notifying your company
 17 of the identification of NDMA on June 5,
 18 2018? Is that why you contacted him?
 19 MR. GALLAGHER: Objection.
 20 Vague, and lacks foundation.
 21 A. The reason -- first of all,
 22 obviously, you know, because we received a
 23 notice and we, you know, need to have an
 24 expertise, you know, to evaluate from the,

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1 you know, toxicological perspective.
 2 And also, as I said, because he
 3 is a long-time friend of mine, and I know he
 4 is a toxicologist, so that's how, you know, I
 5 naturally, you know, thought of him and
 6 turned to him for help.
 7 BY MR. SLATER:
 8 Q. Did you see him as an expert in
 9 toxicology?
 10 A. Oh, yeah, yeah.
 11 Q. Did you consider him somebody
 12 who would provide you reliable information?
 13 A. Yes.
 14 Q. Was he somebody that you
 15 trusted?
 16 A. Oh, yes.
 17 MR. SLATER: Let's scroll up,
 18 Cheryl, to the next e-mail in the
 19 chain on the second page. Perfect.
 20 Q. Now, looking at the June 10,
 21 2018 e-mail sent at 11:49 a.m. from Charles
 22 Wang to yourself, do you see that?
 23 A. Mm-hmm.
 24 Q. I have another question.

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1 Rephrase.
 2 Why is it that you and Charles
 3 Wang were communicating on your Yahoo
 4 accounts rather than on business accounts?
 5 A. I think the main reason is, you
 6 know, he is a long-time friend of mine, and,
 7 you know, we've been using, you know, Yahoo
 8 e-mail or personal e-mail, you know, for
 9 quite long.
 10 So during that time, you know,
 11 because this events was so urgent, right, so
 12 I, you know, did it, you know, just
 13 naturally, you know.
 14 And because, you know, his
 15 Yahoo e-mail is also like sort of like stored
 16 on my, you know, Yahoo, right? So once I
 17 type, you know, like "Charles," that e-mail
 18 naturally will appear.
 19 So, yeah, it's urgent, it's for
 20 convenient. Yeah, that's how it happened.
 21 Q. Did you or anybody else from
 22 ZHP, to your knowledge, contact any other
 23 toxicologists or experts regarding the health
 24 or safety issues with NDMA in June 2018?

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1 A. I don't recall. I mean, for me
 2 I only contacted the Charles Wang. But
 3 anyone else, you know, from ZHP contact
 4 anybody else, I just don't know.
 5 Q. Was Charles Wang the only
 6 outside toxicologist your company consulted
 7 in connection with the NDMA in the valsartan?
 8 A. I cannot -- you know, I do not
 9 have this knowledge like somebody else did.
 10 Q. Is there any other toxicologist
 11 other than Charles Wang that anybody at ZHP
 12 consulted with or spoke to regarding the NDMA
 13 in valsartan?
 14 MR. GALLAGHER: Objection.
 15 Vague.
 16 A. You know, as I said, you know,
 17 from my perspective, I only contact or
 18 consulted with Charles Wang.
 19 BY MR. SLATER:
 20 Q. As part of your preparation to
 21 testify for your company, did you ask others
 22 if they had contacted any other
 23 toxicologists?
 24 A. I haven't asked.

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1 Q. Looking now at the June 10,
 2 2018 e-mail, Charles Wang wrote to you and
 3 said, "Hi Min, The attached is draft report
 4 for NDMA."
 5 A. Mm-hmm.
 6 Q. "I can take out the limit of
 7 0.011 parts per million if you are unable to
 8 achieve it."
 9 Do you see that?
 10 A. Mm-hmm.
 11 Q. So in this report that he
 12 wrote, he put in a maximum acceptable limit
 13 of 0.011 parts per million for on a
 14 going-forward basis, correct?
 15 A. Yes.
 16 Q. And he asked you if you --
 17 he -- rephrase.
 18 And he's asking you here, do
 19 you want me to change it if ZHP can't get to
 20 that level; that's what he's asking you,
 21 correct?
 22 A. Mm-hmm, yes.
 23 Q. Is that what a good scientist
 24 does in providing scientific advice, provide

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1 their opinion and their advice, but then say,
 2 well, I'll change it if for commercial
 3 purposes you need me to?
 4 MR. GALLAGHER: Objection.
 5 Vague.
 6 A. I think your statement is
 7 twisted, you know, the fact. Okay.
 8 At that time, okay, nobody had
 9 any idea like what limit should be set, okay.
 10 So very naturally there would be a
 11 discussion, what would be a reasonable, you
 12 know, you know, limit to set, okay.
 13 So I think that, you know,
 14 based upon the context, you know, everything
 15 is written here, it looks like, you know, the
 16 0.011 ppm was a number, if I remember
 17 correctly, you know, proposed by a Novartis,
 18 you know, toxicologist, okay.
 19 And that person, you know, you
 20 know, derived this number from, I think, an
 21 animal study. It's not based upon rodent,
 22 okay. I think it's based upon, you know, a
 23 primate, maybe monkey or something.
 24 So that, you know, from that

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1 PD50, you know, that person derived a limit
 2 of 0.011 ppm. Okay.
 3 So later, you know, I think if
 4 you look at the European regulatory, you
 5 know, you know, document, you know, they
 6 spent, you know, quite a -- you know, you
 7 know, quite a few, like maybe one page or
 8 whatever, discussing what the value should be
 9 used.
 10 So I think the conclusion or
 11 the eventual consensus is that for those, you
 12 know, animal carcinogenic study, it would
 13 have been more reliable to use, you know, you
 14 know, data from rodent.
 15 The very reason was because
 16 primate -- you know, the lifespan of primate,
 17 you know, is too long, right? You know, so
 18 you would have -- you know, quite a lot of
 19 other factors would impact, you know, how a
 20 tumor would be produced.
 21 So I think, you know, if you
 22 ask somebody, you know, you know, who are
 23 familiar or some, you know, like a
 24 toxicologist who are familiar, you know, with

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1 these issues, you know, or everything that I,
2 you know, you know, you know, are talking
3 about here, you know, people would agree, you
4 know.
5 So that's how the 0.3 ppm,
6 right? It's from a rodent, you know, study.
7 Okay.
8 So yeah, at the very beginning,
9 you know, as I said, even FDA or European
10 regulatory agency, you know, you know, didn't
11 know, you know, how to set, and -- yeah, so
12 it's very -- you know, everything, you know,
13 was progressing, and actually is still, you
14 know, progressing.
15 BY MR. SLATER:
16 Q. Reading along in the e-mail,
17 Charles Wang said, "I can take out the limit
18 of 0.011 ppm if you are unable to achieve it.
19 See if your client accept the limit
20 recommended based on the maximum intake of
21 NDMA via food or exposure of indoor air. The
22 limit of 0.011 ppm is calculated based on the
23 EPA recommended limit for underground water,
24 which won't cause the risk to exceeding the

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1 tumorigenesis rate of 10e-6 in lifespan of
2 human being. Let me know if you any comments
3 or questions."
4 That's what he wrote to you,
5 right?
6 A. Okay. Oh, yeah. So -- yeah,
7 okay. So based upon -- I'm sorry. Yeah,
8 based upon, you know, you know, this whole
9 e-mail, yes.
10 So I take it back, you know,
11 you know, referring the 0.011 ppm, you know.
12 But between Novartis and the
13 ZHP, we did have that communications, you
14 know, in terms of what limit, you know, you
15 know, should be set.
16 So, as I said, the data from,
17 you know, you know, you know, from that
18 primate, it would be lower than 0.3.
19 So, I mean, this 0.011 could be
20 from, you know, the primate, okay, because
21 they are -- you know, both are lower than the
22 0.3.
23 But, you know, in the end, as I
24 said, you know, after, you know, all of the,

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1 you know, you know, discussion progressing,
2 so now regulatory agencies, particularly
3 like, you know, FDA, right, now is setting a
4 limit of 0.3, which is based upon, you know,
5 the rodent carcinogenic study.
6 MR. SLATER: Cheryll, if you
7 could scroll up to the next page so we
8 can get to the beginning of the next
9 e-mail, which starts on the next page,
10 please. Perfect.
11 Q. Later that day now on June 10,
12 2018 at 9:09 p.m., where the prior e-mail had
13 been at 11:49 a.m., Charles Wang writes to
14 you again.
15 Do you see that?
16 A. Mm-hmm.
17 Q. He writes to you to provide you
18 a statement in the ICH M7 guideline.
19 Do you see that?
20 A. Yeah, "TTC-based Acceptable
21 Intakes." Okay. Mm-hmm.
22 Q. And it has some threshold of
23 toxicological concern-based acceptable
24 intakes, and it has some information on that.

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1 Do you see that?
2 A. Yeah, let me read through.
3 TTC-based...
4 (Witness reviewing document.)
5 THE WITNESS: So that's the
6 first paragraph, 7.2, "Based on
7 Compound Specific Risk Assessment."
8 Okay. "Mutagenic Impurities
9 with Positive Carcinogenicity Data
10 (Class 1 in Table 1).
11 Compound-specific risk assessments to
12 derive acceptable intakes should be
13 applied instead of the TTC-based
14 acceptable intake where sufficient
15 carcinogenicity data exist. For a
16 known mutagenic carcinogen, a
17 compound-specific acceptable intake
18 can be calculated" -- "and
19 linear extrapolation as a default" --
20 okay. Yeah.
21 MR. GALLAGHER: Doctor, when
22 you read out loud, the court reporter
23 has to take everything down that
24 you're saying. So just when you're

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1 reviewing the document, for ease of
2 everyone, the document says what it
3 says.
4 THE WITNESS: Okay. I'm sorry.
5 Yeah.
6 Yeah, I finished reading, yes.
7 MR. SLATER: Counsel, I would
8 appreciate it if you would not
9 instruct your witness not to say
10 things out loud.
11 MR. GALLAGHER: I'm not
12 instructing him not to say things. I
13 think he didn't realize.
14 THE WITNESS: Well, yeah, I
15 just read through the e-mail.
16 MR. GALLAGHER: If you feel
17 it's necessary for you to read it out
18 loud, you should read it out loud.
19 I'm not sure if that's what you were
20 intending to do, so...
21 Please proceed.
22 THE WITNESS: Okay.
23 BY MR. SLATER:
24 Q. You can see that after --

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1 rephrase.
2 You can see that in this e-mail
3 Charles Wang says. "Hi Min, See statement in
4 ICH M7 regarding" -- and then you see that's
5 what it says, right?
6 A. Mm-hmm.
7 Q. And then he has some
8 information about acceptable intake levels
9 and it depends on what class somebody is
10 placed in.
11 Do you see that?
12 A. Yes.
13 MR. SLATER: Cheryll, if you
14 could scroll down to the top half of
15 the following page, we'll go to the
16 carryover, and there's a table.
17 Q. And you remember, that table is
18 in the ICH M7 guideline, correct?
19 A. Yes.
20 Q. And we see it says Table 1 --
21 MR. SLATER: Scroll up a
22 millimeter more so we can get the
23 bottom of the e-mail, please. Just a
24 little -- that's it. Perfect.

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1 Q. We see the table, and then you
2 can see underneath that it says, "NDMA should
3 be Class 1 compound" giving it" -- "given
4 its well known mutagenicity nature of this
5 compound. Charles."
6 Do you see that?
7 A. Yes.
8 Q. So he's saying that it should
9 fall into Class 1 under the ICH guidelines,
10 which is defined as a known mutagenic
11 carcinogen, correct?
12 MR. GALLAGHER: Objection.
13 Vague, and calls for speculation.
14 A. It's a known mutagenic
15 carcinogenic to animal.
16 BY MR. SLATER:
17 Q. A Class 1 impurity is defined
18 on this table as a known mutagenic
19 carcinogen, and he's saying NDMA should fall
20 into that class, correct?
21 MR. GALLAGHER: Objection.
22 Vague, calls for speculation, and to
23 the extent it calls for expert
24 testimony.

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1 A. That's what he said.
2 But I should emphasize, in this
3 particular case NDMA is a known mutagenic
4 carcinogen to animal.
5 BY MR. SLATER:
6 Q. Let's go up now to the
7 beginning of the e-mail. Rephrase.
8 Let's go to the beginning of
9 the whole -- rephrase.
10 Let's go to the top now, to the
11 last e-mail in the chain, please.
12 MR. SLATER: Thank you,
13 Cheryll.
14 Q. Looking now at the next e-mail
15 in the chain, June 12, 2018, Charles Wang
16 wrote to you at 3:18, it looks like.
17 Do you see that?
18 A. Yes.
19 Q. And he says -- rephrase.
20 In this e-mail Charles Wang
21 says, "Hi Min, Looks like IARC does consider
22 NDMA as a Class 2A agent. However, according
23 to the definition of Class 2 in ICH M7(R1)
24 guideline, the Class 2 compound should be a

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1 "Known mutagens with unknown carcinogenic
2 potential (bacterial mutagenicity positive*,
3 no rodent carcinogenicity data)."
4 Do you see that?
5 A. Yes.
6 Q. And he actually highlighted the
7 "no rodent carcinogenicity data."
8 Do you see that?
9 A. Let's see. No rodent -- yeah,
10 highlighted, yes.
11 Q. The e-mail continues, "There
12 are plenty rodent carcinogenicity data for
13 NDMA (see revised report in the attached,
14 page 4). In Fisher MSDS, NDMA has been
15 classified as Class 1B for carcinogenicity
16 (attached)."
17 Do you see that?
18 A. Yes.
19 Q. He then says, "Guess you can
20 argue with your client and see if they accept
21 IARC's classification and agree to control
22 the level at threshold of toxicological
23 concern (1.5" -- is that micrograms or
24 milligrams per day?

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1 A. Microgram.
2 Q. And we went over yesterday, and
3 I can pull it out if we need to, that the ICH
4 M7 guideline actually said that's
5 inapplicable to those compounds that are
6 considered to be in the cohort of concern
7 like nitrosamine compounds. Remember we went
8 through that yesterday?
9 MR. GALLAGHER: Objection to
10 the extent it mischaracterizes his
11 testimony.
12 A. Yes, we did went through.
13 MR. SLATER: In fact, Cheryll,
14 let's pull up now as Exhibit 317 the
15 material safety data sheet referred to
16 here by Charles Wang.
17 (Whereupon, Exhibit Number
18 ZHP-317 was marked for
19 identification.)
20 BY MR. SLATER:
21 Q. You know what a material safety
22 data sheet is, correct?
23 A. Yes.
24 Q. What is a material safety data

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1 sheet?
2 A. Well, based upon my
3 understanding, it is a document that
4 typically utilized in the storage and
5 transportation of a chemical.
6 Q. It also provides hazard and
7 risk information about the chemical, correct?
8 A. Right. Being one of the
9 section or two, you know, some of the
10 sections, they talk about -- yeah, that's
11 why, you know, just to help people, you know,
12 to be properly handling, you know, the
13 chemical during the transportation or
14 storage.
15 Q. Looking now at the
16 Classification section, under
17 "Carcinogenicity" it says "Category 1B,"
18 correct?
19 A. I'm sorry, where?
20 MR. SLATER: You've got to
21 scroll up, Cheryll, just to get that
22 box that has the categories in it.
23 Perfect. That's good. Yeah. I don't
24 want to go to the next page. No, I

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1 don't want to go to the next page.
2 Q. Looking at the classification
3 category, I'm just looking to identify what
4 Charles Wang was referring to, he said that
5 it refers to NDMA as a Class 1B.
6 Do you see that?
7 A. Mm-hmm. Yes.
8 MR. GALLAGHER: Objection.
9 MR. SLATER: Okay. We can take
10 that down.
11 A. But I don't know how, you know,
12 this MS --
13 MR. SLATER: Cheryll, you can
14 take that down. We're going to the
15 next document.
16 MR. GALLAGHER: You can
17 complete your answer. And if you need
18 to see the document, we can --
19 BY MR. SLATER:
20 Q. I'll put it back up. I --
21 A. You know, I --
22 Q. If you want to see the document
23 again, I'll go through the whole thing --
24 A. That's fine. But I just need

<p style="text-align: right;">Page 570</p> <p>1 to point out, you know, it looks to me, you 2 know, I don't know -- first of all, I don't 3 know what this Class 1B, you know, in this 4 particular MSDS, you know, they are referring 5 to. 6 Okay. If they are referring to 7 the same, you know, you know, IARC 8 categorization, you know, then it is just not 9 correct, because if they look at the, you 10 know, IARC classification, you know, even as 11 of today, you know, NDMA is classified as 2A, 12 okay. 13 Q. We literally just went through 14 in Exhibit 316 where Charles Wang, who you 15 told us earlier is an expert, someone who is 16 reliable and who you trust, told you that he 17 disagrees with the Class 2A classification. 18 That is what the e-mail said. 19 Is that a correct statement 20 that I just made? Yes or no. 21 A. He -- 22 MR. GALLAGHER: Objection. 23 Calls for speculation, to the extent 24 it mischaracterizes the document and</p>	<p style="text-align: right;">Page 572</p> <p>1 on his Yahoo account, but you're on your work 2 account. Do you know why that is? 3 A. You know, again, I don't 4 remember exactly, you know, you know, you 5 know, you know, that I talked to him or 6 whatever. So I would say a reasonable 7 explanation is, you know, as I explained, you 8 know, right, you know, in the -- during the 9 very early phase, you know, it was quite 10 urgent so I just sent him through my personal 11 e-mail, right. 12 And but then, you know, a few 13 days or, you know, after this event, you 14 know, I probably communicated or talked with 15 him, you know, over the phone or whatever, 16 you know, just I -- I just told him, you 17 know, probably, you know, he should utilize 18 my company e-mail. 19 Q. Looking now at this e-mail, 20 Exhibit 318, Charles Wang writes to you, and 21 in the first paragraph he's providing you 22 some information about some -- a paper and 23 some sort of a reply to a paper. 24 Do you see that?</p>
<p style="text-align: right;">Page 571</p> <p>1 the testimony. 2 A. You know, you know, from the 3 e-mail he just referring to this MSDS, okay. 4 He didn't, you know, you know, you know, go 5 further commenting, you know, on how this 6 Class 1B, you know, was assigned or whether 7 it's -- it may be misleading or this may be 8 incorrect. You know, this is just a -- you 9 know, based upon everything, you know, that I 10 know. 11 MR. SLATER: Okay. Cheryll, 12 I'm going to skip ahead two exhibits 13 in our list to CHARLESWANG000430, 14 please, and we'll make that 15 Exhibit 318. 16 (Whereupon, Exhibit Number 17 ZHP-318 was marked for 18 identification.) 19 BY MR. SLATER: 20 Q. On the screen is Exhibit 318, a 21 June 22, 2018 e-mail from Charles Wang to 22 yourself, correct? 23 A. Yes. 24 Q. Now, in this e-mail he's still</p>	<p style="text-align: right;">Page 573</p> <p>1 A. I'm sorry, what? 2 Q. Rephrase. Withdraw it. 3 MR. SLATER: Could you scroll 4 up, please, Cheryll, a little more so 5 we can capture the -- that's it. 6 Perfect. 7 Q. Looking now at the June 22, 8 2018 e-mail, which we've marked as 9 Exhibit 318, to you, and I want to look, if 10 we could, at the second paragraph of that 11 e-mail, okay? 12 A. Mm-hmm. 13 Q. Charles Wang says, "Hi Min," 14 and then in the second paragraph says, "I 15 suggest Huahai to hire a carcinogenicity 16 expert consultant to perform the analysis, 17 who knows risk assessment of carcinogen and 18 kept updated in regulatory guideline and 19 standards in this field. If needed, I can 20 recommend a couple to you for consideration. 21 "Best, Charles." 22 Do you see that? 23 A. Yes. 24 Q. So he's basically telling you,</p>

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1 I think we need to get somebody in who is a
 2 real high-level expert in this field to help
 3 us out with this project, and he's willing to
 4 reach out to people he knows to try to get
 5 you such an expert, correct?
 6 MR. GALLAGHER: Objection.
 7 Mischaracterizes the document.
 8 A. Yeah, he said he can recommend
 9 a couple, yes.
 10 MR. SLATER: Let's take that
 11 down now. And we're going to go to
 12 Exhibit 319, which is going to be
 13 CHARLESWANG000447.
 14 (Whereupon, Exhibit Number
 15 ZHP-319 was marked for
 16 identification.)
 17 MR. SLATER: If we could, let's
 18 go to the first e-mail in the chain,
 19 which starts at the very bottom of the
 20 second page, please. Perfect.
 21 BY MR. SLATER:
 22 Q. The first e-mail in the chain
 23 starting at the bottom of the second page is
 24 dated July 5, 2018 at 1:50 p.m.

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1 Do you see that?
 2 A. Mm-hmm. Yep.
 3 Q. The e-mail reads, "Hi Jim, Long
 4 time no see. Hope everything is going well."
 5 MR. SLATER: Let's scroll down
 6 to see the rest of the e-mail.
 7 Q. "Friend of mine is looking
 8 forward a consultant in United States to help
 9 them define their product at FDA. Give me a
 10 call if you are interested. My cell number
 11 is" -- and then the cell number is redacted.
 12 Do you see that?
 13 A. Yes.
 14 Q. Then he says -- rephrase.
 15 Then Charles Wang says, "For
 16 your information, I have moved back to US and
 17 still working for GSK" -- that would be
 18 GlaxoSmithKline, correct?
 19 A. Yeah, looks like, uh-huh.
 20 Q. -- "still working for
 21 GlaxoSmithKline in their safety assessment
 22 group in Upper Merion, Pennsylvania. Hope to
 23 meet you again sometimes for catch up.
 24 "Talk to you later and enjoy

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1 your summer.
 2 "Best regards, Charles."
 3 Do you see that?
 4 A. Mm-hmm.
 5 Q. And are you aware that, in
 6 fact, Charles Wang at that time was the
 7 director of safety assessment for
 8 GlaxoSmithKline?
 9 A. I don't know -- I don't
 10 remember his title, but, yeah, it looks --
 11 yeah, he was working, yeah, for GSK.
 12 Q. Did GSK know that in June and
 13 July of 2018 Charles Wang was consulting for
 14 ZHP regarding the NDMA contamination in
 15 valsartan?
 16 MR. GALLAGHER: Objection.
 17 Vague, and calls for speculation.
 18 A. I have no knowledge of that.
 19 BY MR. SLATER:
 20 Q. Did Charles Wang ever say to
 21 you anything to the effect of, I'll do this
 22 for you, but we can't tell my employer, or we
 23 can't let my employer know that I'm
 24 consulting on the side for another

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1 pharmaceutical company?
 2 MR. GALLAGHER: Objection.
 3 Argumentative, and foundation.
 4 A. I don't think this kind of
 5 conversation ever occurred.
 6 BY MR. SLATER:
 7 Q. Why did you consult with
 8 Charles Wang, who was employed another
 9 company, rather than hiring an independent
 10 toxicological consultant?
 11 MR. GALLAGHER: Objection.
 12 Lacks foundation.
 13 A. As I told you, he has been a
 14 long-time friend of mine, okay, and we didn't
 15 know anybody, you know, else in terms of the,
 16 you know, professional toxicologist, right?
 17 And due to the urgency, you know, you know,
 18 of this nature, we had to, you know, invoke
 19 him, right?
 20 I don't know if you understand,
 21 you know, the procedure if you want to hire
 22 somebody, right, from a company. Like, you
 23 know, there's a lot of red tape you have to
 24 go through.

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1 So due to the very urgent
 2 nature, you know, we tried to solve this
 3 problem as soon as possible. So I naturally,
 4 you know, you know, think of him and, you
 5 know, just contact him.
 6 BY MR. SLATER:
 7 Q. When you say "there's a lot of
 8 red tape," red tape at ZHP to hire a
 9 professional consultant who is independent?
 10 MR. GALLAGHER: Objection.
 11 Foundation.
 12 Go ahead.
 13 A. From a company perspective, no
 14 matter, you know, who you hire, okay, you
 15 have to go through certain procedures, right?
 16 Like, you know, a contract for service, you
 17 know, like a confidential, you know,
 18 agreement, whatever. You know, this will
 19 take at least a few days.
 20 But here, you know, because the
 21 urgency, you know, of the nature, right, we
 22 don't want to waste any single day.
 23 BY MR. SLATER:
 24 Q. So you didn't pay Charles Wang

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1 for any of the consulting he did for ZHP?
 2 A. That I have no idea.
 3 Q. You don't know if Charles Wang
 4 was paid for the work he did for ZHP?
 5 A. I have no knowledge of that,
 6 okay, because this is -- you know, this has
 7 been outside of my -- you know, yeah, because
 8 I'm -- as I said, I'm a technical person. I
 9 just reach out to him, you know, you know,
 10 for his help.
 11 Q. Did you ever discuss with
 12 Charles Wang the subject of him being
 13 compensated for consulting for ZHP while he
 14 was employed by GlaxoSmithKline as their
 15 director of safety assessment?
 16 MR. GALLAGHER: Objection.
 17 Lacks foundation.
 18 A. As I said, you know, for this
 19 matter I don't know. I have no idea.
 20 BY MR. SLATER:
 21 Q. You have no idea if you ever --
 22 well, let me ask the question. I want to
 23 make sure I'm clear.
 24 Did you ever ask any --

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1 rephrase.
 2 Did anybody ever tell you that
 3 Charles Wang was paid anything for consulting
 4 for ZHP with regard to the NDMA contamination
 5 of ZHP's valsartan?
 6 A. I don't remember.
 7 MR. GALLAGHER: Objection.
 8 Foundation.
 9 BY MR. SLATER:
 10 Q. That would be pretty easy to
 11 find out, right? If we requested that from
 12 you, your company should have a record if
 13 they paid him, right?
 14 MR. GALLAGHER: Objection.
 15 Lacks foundation.
 16 A. You can -- I would say you can
 17 make, you know, a request, right, just like
 18 Patrick said. You can make a request, you
 19 know, through all counsel. They can find out
 20 for you.
 21 BY MR. SLATER:
 22 Q. Would Jun Du know if Charles
 23 Wang was paid for the work he did for ZHP?
 24 MR. GALLAGHER: Objection.

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1 Calls for speculation.
 2 A. You can ask him, okay?
 3 BY MR. SLATER:
 4 Q. Did you ever speak to the
 5 chairman of your company, Mr. Chen, regarding
 6 any of your interactions with Charles Wang
 7 and what he was telling you?
 8 A. No.
 9 Q. Did you ever speak to Baohua
 10 Chen at all about the nitrosamine
 11 contamination of valsartan sold by ZHP? Did
 12 you ever discuss that with him?
 13 A. We discussed the matter, you
 14 know, in meetings.
 15 Q. Meetings in person?
 16 A. No, not in person.
 17 Q. How were those meetings held?
 18 A. I mean, like, you know, when
 19 this event basically occurred, you know, you
 20 know, it become the top priority of the
 21 company.
 22 So as the CEO of the company,
 23 you know, you know, he organized, you know,
 24 quite a few meetings, basically just to

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1 ensure, you know, the investigation being
2 conducted, you know, as soon as possible,
3 and, you know, basically just ask us, you
4 know, what kind of resources that we need,
5 basically.

6 Q. Were those meetings that you
7 talked about held in person? Well, rephrase.

8 You said the meetings were not
9 held in person. So how were they held?

10 A. You know, with a group, like,
11 you know, with a group of peoples.

12 Q. Was it over the telephone? Was
13 it by videoconference? How did you
14 communicate with one another in those
15 meetings?

16 A. Sir, as I said, there are
17 different meetings, okay? Some meetings, I
18 don't -- you know, I don't remember, you
19 know, you know, all the details. But some
20 meetings, you know, all the participants, you
21 know, were attending in person, some meetings
22 probably, you know, involving some
23 telecommunications.

24 Q. So you did have meetings in

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1 person with Mr. Chen about the nitrosamine
2 contamination of the valsartan?

3 A. Well, in person, okay, I
4 thought you mean like, like, just, you know,
5 like one-on-one meeting, you know. But,
6 yeah, like a -- when -- a group of meeting,
7 yeah, both Mr. Chen and I as well as other
8 members of the management, yeah. Yeah, at
9 least, you know, yeah, we were attending some
10 of the meeting, you know, when both Mr. Chen
11 and myself were physically, you know,
12 attending the meetings.

13 Q. So you said meetings took place
14 in person, right?

15 A. Some meeting, yeah, some
16 meeting, yeah, were attended in person, yes.

17 Q. Were some of the meetings by
18 videoconference?

19 A. Yeah, uh-huh. Not
20 videoconference. I don't think you -- you
21 know, you -- we don't have videoconference,
22 usually just teleconference.

23 Q. You said usually
24 teleconference. Did at least one of the

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1 meetings involving Mr. Chen regarding the
2 nitrosamine contamination of the valsartan
3 take place over videoconference?

4 A. I don't remember that ever
5 happened.

6 MR. GALLAGHER: Adam, we've --
7 you can finish -- we've been going
8 about an hour and 20 minutes. When
9 you get to a natural --

10 BY MR. SLATER:
11 Q. Did any of the meetings take
12 place by telephone?

13 A. As I said, some of the meeting
14 may, you know, may be held, you know, with
15 some attendants, okay, joining by
16 teleconference.

17 Q. Teleconference means by
18 telephone?

19 A. Yeah, by telephone, yes.

20 Q. Did you attend every meeting
21 that Mr. Chen organized and attended
22 regarding the nitrosamine contamination of
23 ZHP's valsartan?

24 A. I don't think so, like did I

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1 attended every meeting, because there's a
2 different, you know, you know, you know,
3 aspects dealing with this issue, right.

4 And, for example, the issue
5 regarding like recall, you know, because I --
6 you know, as I said, I'm a technical person,
7 those meetings, you know, I never attended,
8 you know, those kind of meetings because it's
9 outside of my scope, outside of my
10 responsibility.

11 Q. You said --

12 A. Yeah.

13 Q. You said that Mr. Chen
14 organized meetings because he was the CEO.
15 So you don't know how many meetings took
16 place or who attended all those meetings?

17 MR. GALLAGHER: Objection.
18 Calls for speculation.
19 Go ahead.

20 A. As I said, you know, I -- those
21 information I'm not, you know, within my
22 responsibility, okay.

23 BY MR. SLATER:
24 Q. Well, I'm not asking for your

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1 responsibility. I'm asking if you know how
 2 many meetings took place and who attended
 3 each of them.
 4 A. I don't --
 5 MR. GALLAGHER: Objection.
 6 Calls for speculation.
 7 A. I don't remember.
 8 BY MR. SLATER:
 9 Q. How many meetings did you
 10 attend with Mr. Chen regarding the
 11 nitrosamine contamination of ZHP's valsartan?
 12 A. Again, I don't have accurate
 13 numbers.
 14 Q. Was it 10 meetings, was it 20
 15 meetings? Can you estimate, please?
 16 A. I just cannot.
 17 Q. You have no idea how many
 18 meetings you attended with Mr. Chen?
 19 A. I don't keep, you know, you
 20 know, you know, those things.
 21 Q. I'm just asking if you can
 22 recall how many meetings. You said this was
 23 top priority of the company at the time. I
 24 would think you could recall roughly how many

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1 meetings you attended with the chairman of
 2 the company about this crisis.
 3 MR. GALLAGHER: Objection.
 4 Argumentative, and asked and answered.
 5 BY MR. SLATER:
 6 Q. Can you recall?
 7 A. No, I cannot recall the
 8 accurate number.
 9 Q. Can you give me an estimate?
 10 MR. GALLAGHER: Objection.
 11 Asked and answered.
 12 A. As I said, you know, I don't
 13 want to provide -- you know, you know,
 14 because I don't have this memory, so I don't
 15 want to, you know, provide any specific
 16 number, okay?
 17 BY MR. SLATER:
 18 Q. Well, can you tell me your best
 19 estimate, please, or are you unwilling to do
 20 so?
 21 MR. GALLAGHER: Objection.
 22 Argumentative, and asked and answered.
 23 A. So if you want to say, you
 24 know, the best estimate by now, you know, you

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1 know, at this time I would say probably, you
 2 know, maybe single digit or maybe up single
 3 digit.
 4 BY MR. SLATER:
 5 Q. What does that mean, "single
 6 digit or maybe up single digit"?
 7 A. Like, you know, anywhere like
 8 maybe between five or nine or something like
 9 that.
 10 Q. Do you recall what was
 11 discussed in those meetings?
 12 A. As I said, I don't, you know,
 13 recall all the exact, you know, you know, you
 14 know, contents. Basically, you know, you
 15 know, the instruction was, you know, we need
 16 to, you know, put all the efforts -- you
 17 know, the company will support utilizing all
 18 the resources, you know, to push this forward
 19 as soon as possible.
 20 Q. Using all the resources -- I'm
 21 sorry.
 22 When you say using all the
 23 resources, did that include making sure that
 24 there wouldn't be any "red tape" like you

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1 said before if you needed to hire an expert
 2 consultant to advise the company, for
 3 example, on toxicology?
 4 MR. GALLAGHER: Objection.
 5 Lack of foundation.
 6 A. This topic was not discussed,
 7 okay. So in terms of the resources, from my
 8 perspective, okay, it was, you know, you
 9 know, we need to -- we need to purchase
 10 additional, you know, high-end instrument,
 11 okay, particularly like a mass spectrometry,
 12 a GC-MS, GC-MS/MS, you know, stuff like that.
 13 So he indicated he will give the full
 14 support, like, you know, as long as, you
 15 know, yeah, like how many, whatever, you
 16 know, whenever that I, you know, propose he
 17 will, you know, approve the purchase of these
 18 instrument.
 19 BY MR. SLATER:
 20 Q. Were notes or minutes taken of
 21 these meetings with Mr. Chen?
 22 A. I don't remember.
 23 Q. Did you take notes of these
 24 meetings?

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1 A. No.

2 Q. Did you see anybody else taking

3 notes during these meetings?

4 A. I didn't pay attention to that.

5 Q. So you would go to meetings

6 with the chairman of the company about a

7 situation that was the top priority of the

8 company, and you wouldn't take any notes

9 during those meetings at all?

10 MR. GALLAGHER: Objection.

11 Argumentative.

12 And we're getting close to --

13 towards an hour and a half, if you get

14 close to a breaking point.

15 A. I didn't take note.

16 BY MR. SLATER:

17 Q. Is that your typical practice,

18 you go to important meetings and you take no

19 notes at all?

20 MR. GALLAGHER: Objection.

21 Vague, and argumentative.

22 A. Because those meetings, you

23 know, you know, from my perspective, as I

24 said, you know, it's very specific, okay.

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1 Because for me, I just need to have the

2 funding to purchase these instrument, so, you

3 know, for these simple things I don't think

4 it's necessary, you know, for me to take

5 note. You know, he just, yes, you know, then

6 go ahead.

7 BY MR. SLATER:

8 Q. Are you saying that you had

9 five to nine meetings, which is your

10 estimate, and at every one you discussed

11 buying equipment to do testing, and that was

12 the whole meeting every time? You're not

13 saying that, are you?

14 A. No, I'm not saying that.

15 MR. GALLAGHER: Objection.

16 BY MR. SLATER:

17 Q. Do you remember what else was

18 discussed in those meetings with Mr. Chen,

19 the chairman of the company?

20 A. Look, you know, as I said, I

21 don't remember, you know, exactly, you know,

22 you know, all the other things, okay.

23 The most obvious things is, or

24 the most clear thing is that Mr. Chen was

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1 fully support, okay, in terms of, you know,

2 allocating funding, you know, for the

3 instrument, you know, that I need.

4 The other meeting, it's most

5 likely he was asking, you know, for our

6 progress, for example, how the method

7 development was ongoing, you know, stuff like

8 that.

9 Q. Okay. Did Mr. Chen say any --

10 well, rephrase.

11 Did Mr. Chen ever tell you or

12 the people in your meetings -- rephrase.

13 During the meetings you

14 attended with Mr. Chen, did he take notes?

15 Did you ever see him taking notes?

16 A. No.

17 Q. Did anybody take notes in these

18 meetings that you ever observed?

19 A. I just pay attention mostly to

20 Mr. Chen when I spoke, you know, to him.

21 Q. When you were in these

22 meetings, did you ever notice anybody in the

23 meetings taking notes?

24 A. I don't re --

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1 MR. GALLAGHER: Objection.

2 Go ahead.

3 A. I don't recall, okay?

4 BY MR. SLATER:

5 Q. So a roomful of people meeting

6 with the chairman of the company about a

7 situation that's the top priority of the

8 company multiple times, in all those meetings

9 you never took notes, Mr. Chen never took

10 notes, and you never saw anyone else take

11 notes.

12 That's your best recollection,

13 is that what you're testifying?

14 MR. GALLAGHER: Objection.

15 Argumentative, asked and answered,

16 vague, and compound.

17 A. That's not what exactly what I

18 told you. Okay. What I can tell you is

19 Mr. Chen, he didn't take notes, okay? And I

20 didn't take note. Who else, I don't

21 remember, okay?

22 BY MR. SLATER:

23 Q. Were there ever agendas

24 circulated for these meetings; for example,

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1 by e-mail?

2 A. I don't know. I don't

3 remember.

4 Q. When these meetings were

5 scheduled, were e-mails sent out or any sort

6 of calendar sent out so everybody would know

7 the date and time and place of the meetings?

8 A. I don't remember. I mean, but

9 one thing is, you know, usually, okay, I can

10 tell you my -- you know, like for Mr. -- you

11 know, for meetings with Mr. Chen, usually,

12 you know, his, you know, secretary, you know,

13 would make phone calls.

14 And one of the reason probably

15 was he was quite busy, so we just -- you

16 know, a lot of times we just stand by. And

17 so once he had time, his secretary would

18 call, call us, you know, to go to meeting

19 rooms, you know, with him.

20 Q. Who was his secretary? What's

21 her name?

22 A. There is a --

23 Q. Who is Mr. Chen's secretary?

24 A. There are a group, you know, of

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1 people, okay. I don't know exactly, you

2 know, who would be designated.

3 I think the best, you know,

4 answer, if you can, you know, maybe you can

5 also go through my counsel, you know, making

6 a formal request, they can provide it, you

7 know, from the staff of Mr. Chen. You know,

8 they probably can give you, you know, a much

9 more accurate, you know, because I don't want

10 to, you know, you know, guess.

11 Q. You know who works for

12 Mr. Chen. Tell us the names of the people

13 that work for him as his secretaries and

14 assistants.

15 MR. GALLAGHER: Objection.

16 Asked and answered.

17 And, Adam, we've been going

18 over an hour and a half now.

19 MR. SLATER: I'm in the middle

20 of a line of questioning. I don't

21 want to break this deposition now. I

22 don't think it would be appropriate.

23 MR. GALLAGHER: I'm not sure

24 where you're going, but okay.

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1 A. His chief of staff, okay, is

2 Ms. Maggie Kong, as I mentioned the other

3 day.

4 BY MR. SLATER:

5 Q. Is she the person who would

6 call you to tell you meetings were being

7 scheduled?

8 A. Sometimes she called me;

9 sometimes, you know, her staff.

10 Q. Who are the staff members that

11 worked for her who would contact you?

12 A. You know, there would be

13 different, you know, people, okay, so I don't

14 remember, you know, you know, very

15 specifically for, you know, exactly, you

16 know, who under her, you know, called me,

17 okay?

18 Q. Can you remember anybody else's

19 name that contacted you, other than Maggie

20 Kong?

21 A. I mean, you know, this is for

22 so long, so I couldn't, you know, give you an

23 accurate. You know, I don't want to provide,

24 you know, you know, you know, anything, you

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1 know, inaccurate, okay.

2 So only thing for sure, you

3 know, yeah, it would be somebody -- you know,

4 yeah, sometimes could be her; sometimes, you

5 know, could be someone, you know, you know,

6 of her staff.

7 Q. After these meetings would take

8 place, what would Mr. Chen do in terms of

9 taking action based on the meetings?

10 MR. GALLAGHER: Objection.

11 Lack of foundation, and calls for

12 speculation.

13 A. I don't pay attention to, you

14 know, other things, as I said, you know,

15 because my, you know, main function or my

16 main responsibility was to ensure the

17 technical investigation, you know, move

18 forward as soon as possible.

19 BY MR. SLATER:

20 Q. Did Mr. Chen give any

21 instructions at these meetings? Other than

22 you said he said, okay, you can buy that

23 machine that you were asking about, did he

24 ever give any other instructions?

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1 A. As I said, I don't --
 2 MR. GALLAGHER: Objection.
 3 Lacks foundation.
 4 A. As I said, you know, my only
 5 focus, you know, was, you know, you know, for
 6 the part of the responsibility, you know,
 7 from my perspective.
 8 BY MR. SLATER:
 9 Q. Was Mr. Chen aware that at
 10 least as of July 27, 2017 there were people
 11 in your company that knew that NDMA was in
 12 valsartan that your company was selling?
 13 A. He had no idea.
 14 MR. GALLAGHER: Objection. No
 15 foundation.
 16 BY MR. SLATER:
 17 Q. How do you know he had no idea?
 18 A. Because I told you, you know,
 19 as I told you before already, okay.
 20 Q. Did anybody who either sent or
 21 received that e-mail ever tell Mr. Chen or
 22 tell someone else who told Mr. Chen about
 23 that?
 24 MR. GALLAGHER: Objection.

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1 BY MR. SLATER:
 2 Q. Do you know?
 3 MR. GALLAGHER: Objection.
 4 Vague, and lacks foundation.
 5 A. As I said, I -- you know, I
 6 don't remember, or I don't know, you know,
 7 who else on that e-mail list, you know, what
 8 they did afterwards.
 9 BY MR. SLATER:
 10 Q. You don't know if Mr. Chen was
 11 aware that your company knew about the NDMA
 12 in the valsartan as of July 2017?
 13 MR. GALLAGHER: Objection.
 14 Vague, lacks foundation, and
 15 mischaracterizes the documents and
 16 testimony.
 17 A. I'm pretty sure he -- you know,
 18 he didn't know. Otherwise, you know, he
 19 probably, you know, will talk to me.
 20 BY MR. SLATER:
 21 Q. Why do you say that?
 22 A. Well, because, you know, if
 23 it's really, you know, you know, you know,
 24 you know, a big issue, you know, yeah,

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1 he will. You know, particularly, you know,
 2 this is, you know, right, related to an
 3 investigation of an impurity, right?
 4 Mr. Chen, you know, you know,
 5 he is just at the very top. He wouldn't, you
 6 know, have those details, information,
 7 unless, you know, you know, you know, I
 8 became aware, and then I, you know, will
 9 report that to him, or somebody like from QA
 10 or whatever.
 11 But as I said, you know, if
 12 people on that list, you know, they -- you
 13 know, they feel or whatever, you know, this
 14 is an issue, or they may not. As I said, you
 15 know, they may -- they may not, you know, or
 16 they think, you know, Mr. Lin's claim may be,
 17 you know, way exaggerated.
 18 Q. Well, his claim wasn't
 19 exaggerated. He was 100 percent accurate
 20 about valsartan containing NDMA, correct?
 21 MR. GALLAGHER: Objection.
 22 Wait, Min.
 23 THE WITNESS: Sorry.
 24 MR. GALLAGHER: Objection.

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1 Vague, lacks foundation, calls for
 2 speculation, and mischaracterizes
 3 documents and testimony.
 4 A. I think I answered this
 5 question, you know, several times, okay.
 6 BY MR. SLATER:
 7 Q. Did you tell Mr. Chen that in
 8 April of 2018 you told Mr. Lin, who worked
 9 for you, not to complete or not to issue --
 10 rephrase.
 11 Did you tell Mr. Chen at any
 12 time that in April 2018 you told Mr. --
 13 rephrase.
 14 Did you tell Mr. Chen at any
 15 time that in April 2018 you directed that a
 16 report that had been written regarding
 17 concern about nitrosamines in irbesartan, and
 18 you had instructed that that report not be
 19 issued because of the fact that the impurity
 20 was sensitive?
 21 Did you tell Mr. Chen that?
 22 A. No.
 23 MR. GALLAGHER: Objection.
 24 THE WITNESS: Sorry.

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1 MR. GALLAGHER: Objection.
 2 Outside the scope, vague, compound,
 3 and lacks foundation.
 4 A. The answer is no.
 5 BY MR. SLATER:
 6 Q. You said that Mr. Chen was
 7 organizing these meetings. Based on your
 8 understanding and what you observed, was he
 9 very actively interested in what was
 10 happening with the contamination of valsartan
 11 with nitrosamines?
 12 A. As I've said, that he is on top
 13 of the progress, okay? He didn't know, you
 14 know, all those technical details. It's not
 15 his job.
 16 I just want to make sure --
 17 yeah.
 18 Q. I'm sorry.
 19 How do you know he didn't know
 20 the technical details?
 21 MR. GALLAGHER: Objection.
 22 Vague, and calls for speculation.
 23 A. He is the CEO of the company.
 24 So if you talk to head -- like a CEO of

Page 603

1 Novartis, you know, he would -- would that
 2 person know the technical details of NDMA?
 3 BY MR. SLATER:
 4 Q. I don't know if -- I don't
 5 know, if it turned out that NDMA was
 6 contaminating one of their drug substances
 7 and that substance -- and the NDMA was
 8 carcinogenic, yeah, I would think the
 9 Novartis CEO would want to know everything
 10 about it, if you're asking me.
 11 MR. GALLAGHER: Objection.
 12 Wait. Wait, Min.
 13 Objection. Vague,
 14 hypothetical, calls for speculation.
 15 BY MR. SLATER:
 16 Q. Do you know that --
 17 MR. GALLAGHER: Just for the
 18 record, we've been going for an hour and
 19 40 minutes now, and I'm sure the court
 20 reporter would love a break, but --
 21 BY MR. SLATER:
 22 Q. Do you know that Mr. Chen --
 23 MR. GALLAGHER: -- your
 24 deposition.

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1 BY MR. SLATER:
 2 Q. Do you know that Mr. Chen has a
 3 master's in chemical engineering?
 4 A. That I --
 5 MR. GALLAGHER: Objection.
 6 A. Sorry.
 7 BY MR. SLATER:
 8 Q. Do you know that Mr. Chen has a
 9 background in chemistry or chemical
 10 engineering? Are you aware of that?
 11 MR. GALLAGHER: Objection.
 12 Outside the scope.
 13 A. I know he at least had a
 14 college degree, okay, but everything else I
 15 really didn't pay attention.
 16 MR. SLATER: You can take a
 17 break now. Go off the record.
 18 THE VIDEOGRAPHER: The time
 19 right now is 8:47 a.m. We're now off
 20 the record.
 21 (Whereupon, a recess was taken)
 22 THE VIDEOGRAPHER: The time
 23 right now is 9:05 a.m. We're back on
 24 the record.

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1 BY MR. SLATER:
 2 Q. Do you know -- well, wait a
 3 second.
 4 Do you know whether any record
 5 was made of Mr. Chen's interactions with
 6 other people in the company about the
 7 valsartan contamination?
 8 A. I have no idea.
 9 MR. GALLAGHER: Objection.
 10 Calls for speculation, and
 11 foundation -- lack of foundation.
 12 BY MR. SLATER:
 13 Q. Can you recall, other than
 14 discussing the equipment that you needed,
 15 anything else that you told Mr. Chen
 16 connected to the valsartan contamination with
 17 nitrosamines?
 18 A. I'm sorry, say that again?
 19 Q. Sure.
 20 Do you remember anything you
 21 told Mr. Chen regarding the nitrosamine
 22 contamination of valsartan?
 23 Earlier you told us you
 24 discussed some equipment you needed.

<p style="text-align: right;">Page 606</p> <p>1 Anything else?</p> <p>2 A. As far as I can remember, you</p> <p>3 know, those are the items that I -- was</p> <p>4 the -- you know, was the main topic.</p> <p>5 Everything else I really, you know, do not</p> <p>6 recall.</p> <p>7 But instrument, you know, was</p> <p>8 really an urgent needs because we need to,</p> <p>9 you know, have those instruments to be in</p> <p>10 place.</p> <p>11 Q. What instrument --</p> <p>12 A. Sorry --</p> <p>13 Q. What instrument or instruments</p> <p>14 did you discuss the need for?</p> <p>15 A. GC-MS, and also GC-MS/MS in</p> <p>16 particular, at least initially. And then</p> <p>17 later on there's also -- I think, you know,</p> <p>18 we discussed like some LC-MS equipment.</p> <p>19 Q. Didn't you already have a GC-MS</p> <p>20 machine?</p> <p>21 A. That --</p> <p>22 MR. GALLAGHER: Objection.</p> <p>23 A. Sorry, go ahead. I'm sorry.</p> <p>24 You know, we were facing with</p>	<p style="text-align: right;">Page 608</p> <p>1 kept asking for an answer from ZHP and</p> <p>2 couldn't get an answer?</p> <p>3 MR. GALLAGHER: Objection.</p> <p>4 Lacks foundation, and mischaracterizes</p> <p>5 documents and testimony.</p> <p>6 A. Such detail, you know, such</p> <p>7 technical details were never discussed, you</p> <p>8 know, at, you know, Mr. Chen's level.</p> <p>9 BY MR. SLATER:</p> <p>10 Q. Was there discussion about how</p> <p>11 your company should -- rephrase.</p> <p>12 In these meetings with</p> <p>13 Mr. Chen, was there discussion about how your</p> <p>14 company should interact with the FDA?</p> <p>15 MR. GALLAGHER: Objection.</p> <p>16 Outside the scope.</p> <p>17 THE WITNESS: Pardon. Go</p> <p>18 ahead.</p> <p>19 MR. GALLAGHER: Objection.</p> <p>20 Outside the scope.</p> <p>21 To the extent you know</p> <p>22 personally, Mr. Li, you should answer.</p> <p>23 A. Anything as far as I know,</p> <p>24 anything, you know, relating to interacting</p>
<p style="text-align: right;">Page 607</p> <p>1 thousands, you know, batches of valsartan</p> <p>2 need to be tested, okay, so a single, you</p> <p>3 know, GC-MS, you know, would not be</p> <p>4 sufficient, right.</p> <p>5 And also that, you know,</p> <p>6 particular GC-MS also was needed, you know,</p> <p>7 to develop and optimize, you know, analytical</p> <p>8 methods. So we need to place the GC-MS also</p> <p>9 in the QC. Because in QC, in Chuannan CC</p> <p>10 there had been no GC-MS instrument, so we</p> <p>11 need to put these, you know, instrument into</p> <p>12 Chuannan QC site, right.</p> <p>13 So eventually, you know,</p> <p>14 Chuannan QC site became the, you know, the</p> <p>15 main testing site for those, you know,</p> <p>16 thousands batches of commercial, you know,</p> <p>17 batches of the valsartan.</p> <p>18 BY MR. SLATER:</p> <p>19 Q. Was Mr. Chen told during these</p> <p>20 meetings that multiple customers of ZHP had</p> <p>21 since 2014 been complaining that there was</p> <p>22 unknown peaks and interference on</p> <p>23 chromatograms, and they were concerned about</p> <p>24 what impurities might be there, and that they</p>	<p style="text-align: right;">Page 609</p> <p>1 with regulatory agencies was taken care of by</p> <p>2 the RA department. Mr. Chen would not have,</p> <p>3 you know, such detailed knowledge, you know,</p> <p>4 how to interact.</p> <p>5 BY MR. SLATER:</p> <p>6 Q. How do you know that? Do</p> <p>7 you -- did you attend the meetings with the</p> <p>8 regulatory people that he attended?</p> <p>9 A. I don't remember. But as I</p> <p>10 said, based upon my, you know, my</p> <p>11 observation, okay, he just would not be</p> <p>12 involved in too much, you know, operational</p> <p>13 details, okay. He's only pay attention to</p> <p>14 high levels, okay, like every --</p> <p>15 Q. One of your very profitable</p> <p>16 drugs was contaminated with something that</p> <p>17 caused cancer. That's about as high level as</p> <p>18 it gets, right?</p> <p>19 MR. GALLAGHER: Objection.</p> <p>20 Argumentative.</p> <p>21 A. I don't want to comment on</p> <p>22 that, okay.</p> <p>23 BY MR. SLATER:</p> <p>24 Q. Do you know whether or not</p>

<p style="text-align: right;">Page 610</p> <p>1 Mr. Chen ever discussed with anybody how your 2 company should interact with the FDA? 3 A. I don't remember -- sorry. 4 MR. GALLAGHER: Objection. 5 Outside the scope, and asked and 6 answered. 7 A. I don't remember. 8 BY MR. SLATER: 9 Q. At any of these meetings that 10 you attended, did Mr. Chen ever ask you, how 11 did this happen, and ask for an explanation 12 for how this could happen? 13 MR. GALLAGHER: Objection. 14 Vague. 15 BY MR. SLATER: 16 Q. Time out. I'm going to ask the 17 question again because counsel said it's 18 vague, so in case, in case, you know, that 19 objection will be sustained I'm going to ask 20 the question again. 21 Did Mr. Chen ever ask you, how 22 was it that our valsartan could be 23 contaminated with a nitrosamine and we didn't 24 know about it? Did he ever ask that</p>	<p style="text-align: right;">Page 612</p> <p>1 BY MR. SLATER: 2 Q. Did you tell Mr. Chen that in 3 multiple drafts the deviation investigation 4 report stated that your company had 5 insufficiently researched and studied the 6 chemical processes, and then somebody made 7 the decision to take that language out of the 8 report before the report was finalized? Did 9 you or anyone tell them that, to your 10 knowledge? 11 MR. GALLAGHER: Objection. 12 Vague, and argumentative. 13 A. I don't remember those details. 14 But my guess is, you know, such details would 15 not be discussed during those meetings 16 usually. 17 BY MR. SLATER: 18 Q. Did you or anybody else in your 19 presence tell Mr. Chen that your company 20 failed to sufficiently research or study the 21 chemical processes, and that's why your 22 company didn't know that NDMA was a potential 23 contaminant from the beginning? 24 MR. GALLAGHER: Objection.</p>
<p style="text-align: right;">Page 611</p> <p>1 question? 2 A. I don't remember specifically, 3 okay, he -- like he specifically asked that 4 question, okay. But I can tell you at least 5 in one of those meetings like, like I 6 explained to everyone, you know, you know, 7 the root cause analysis as we put into this 8 deviation report. 9 Q. When you say the deviation 10 report, you mean the deviation investigation 11 reports that were provided to the FDA? 12 A. Yes. 13 MR. GALLAGHER: Objection. 14 Lacks foundation. 15 A. The deviation report actually, 16 you know, you and I, we just went through, 17 you know, an early draft version. Yeah, I 18 think that -- that's the deviation, you know, 19 investigation report. 20 But what you presented, you 21 know, was only -- you know, looks like an 22 early version. It's not the final, finalized 23 version. 24 ///</p>	<p style="text-align: right;">Page 613</p> <p>1 Vague, lacks foundation, and 2 argumentative. 3 A. As I said, you know, you know, 4 whatever the background information provided 5 in the deviation, you know, in that deviation 6 investigation report, you know, I remember 7 that, that I, you know, as I said, I give a 8 description or, you know, basically went 9 through that some of those contents in the 10 deviation, you know, introduction part. 11 BY MR. SLATER: 12 Q. Did anybody -- rephrase. 13 Did you or anybody else, to 14 your knowledge, tell Mr. Chen that your 15 company was aware that the valsartan your 16 company was selling was contaminated with 17 NDMA long before it came out in June of 2018 18 to the public? 19 MR. GALLAGHER: Objection. 20 Vague, and lacks foundation. 21 A. As I told you, you know, I 22 mean, people attended -- you know, I mean, 23 basically, you know, we didn't know, I mean, 24 you know, at a high level, before the events.</p>

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1 BY MR. SLATER:
2 Q. What do you mean, "we didn't
3 know at a high level"?
4 A. You know, for those people, you
5 know, attending, you know, the meetings.
6 Q. Well --
7 A. As I said, nobody except
8 Mr. Chen -- sorry, Mr., you know, Lin, as I
9 said, he made some guess, you know, out of,
10 you know, you know, some irbesartan, you
11 know, experiment, right? He's making some --
12 his projections, you know.
13 Nobody else -- you know, nobody
14 else, you know, know, you know, there was an
15 issue, until, you know, June the 6th, 2018.
16 Q. Just to be clear, Mr. Lin
17 stated July 27, 2017 that what he was seeing
18 with irbesartan was similar to the NDMA that
19 occurs in valsartan when quenched with sodium
20 nitrite. That's what he said in the e-mail.
21 And you knew that because it
22 was in the e-mail that was sent to you, so
23 you had that information, correct?
24 MR. GALLAGHER: Objection.

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1 Compound, lacks foundation, and
2 mischaracterizes documents.
3 A. As I told you before, you know,
4 for some reason that e-mail just slipped
5 through, you know. So I -- you know, I had
6 no memory, I don't, you know, know until, you
7 know, you just showed me a few days ago, like
8 the day before.
9 BY MR. SLATER:
10 Q. Well, if you had no e-mail, why
11 do you keep telling me that this was some
12 sort of a guess or something else or
13 speculation by Mr. Lin if you don't remember
14 it?
15 A. Well, based upon -- you know,
16 now, based upon the --
17 MR. GALLAGHER: Wait.
18 THE WITNESS: Sorry.
19 MR. GALLAGHER: Objection.
20 Argumentative, and asked and answered.
21 A. You know, it's basically, yeah,
22 based upon that e-mail, yeah, now you provide
23 to me, by reading through. Right? You
24 provide me, you know, the day before, you

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1 know, that e-mail, right? Yeah, I just read
2 through, you know, it looks like, you know,
3 he's making his projections.
4 BY MR. SLATER:
5 Q. Well, he wasn't projecting
6 regarding valsartan. He was stating it as a
7 fact that it's known that NDMA occurs in
8 valsartan when quenched with sodium nitrite.
9 And that statement in his
10 e-mail was scientifically accurate, correct?
11 MR. GALLAGHER: Objection.
12 Lacks foundation, compound, and
13 mischaracterizes documents.
14 A. As I told you, if you look
15 through that e-mail, okay, the data that he
16 had, okay, based upon -- you know, again,
17 based on content of that e-mail, the data
18 that he had were from the experiment with
19 irbesartan, okay?
20 There's no -- there's no data
21 mentioned with anything, like, related to,
22 you know, valsartan, right?
23 I mean, can you see, you know,
24 from the very beginning, go through this

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1 whole document? You know, I don't see it.
2 BY MR. SLATER:
3 Q. He didn't actually -- rephrase.
4 What he said was that he was
5 seeing with the irbesartan was similar to the
6 NDMA that occurs in valsartan when quenched
7 with sodium nitrite.
8 He didn't need to present data
9 in this e-mail because that was a fact he was
10 reciting in the e-mail which was accurate.
11 A. No, no, no. The --
12 MR. GALLAGHER: Wait.
13 THE WITNESS: Sorry.
14 MR. GALLAGHER: Objection.
15 Lacks foundation, vague, and
16 mischaracterizes the document.
17 A. The only data or external
18 information or publicly available information
19 related to valsartan, you know, if you can
20 see, is related to that patent, right. So
21 that patent is actually, you know, referring
22 to, you know, impurity K in valsartan. Okay?
23 BY MR. SLATER:
24 Q. This was internal information

<p style="text-align: right;">Page 618</p> <p>1 that wasn't being shared with anybody from 2 outside the company, this e-mail from July 3 2017. It's an internal e-mail, right? 4 A. Yeah, it is internal e-mail, 5 yeah. 6 Q. And when -- rephrase. 7 When that e-mail states that 8 NDMA occurs in valsartan when it's quenched 9 with sodium nitrite, that's an accurate 10 statement. That's actually the root cause of 11 the NDMA contamination, right? 12 MR. GALLAGHER: Objection. 13 Lacks foundation, and mischaracterizes 14 the document. 15 A. I'm not sure exactly, you know, 16 based upon -- you know, based upon that 17 particular wording, you know. 18 But, you know, to me, you know, 19 when he said quenching with, you know, 20 valsartan, you know, quenching with sodium 21 nitrite, right, the only -- as I said, you 22 know, the available, you know, information, 23 it looks like is the attachment of that 24 external patent.</p>	<p style="text-align: right;">Page 620</p> <p>1 Did anybody in your company 2 identify NDMA through chromatography prior to 3 July 27, 2017 where you were made aware that 4 it had been identified on the test? 5 A. Before -- I'm sorry. Before 6 which date? 7 Q. Before the e-mail sent by 8 Mr. Lin on July 27, 2017. 9 MR. GALLAGHER: Objection. 10 Lack of foundation. 11 A. I was not aware. 12 BY MR. SLATER: 13 Q. Was anybody in your company 14 aware of that, that -- 15 A. I -- 16 MR. GALLAGHER: Objection. 17 BY MR. SLATER: 18 Q. Was anyone in your company 19 aware of a test result that you know of that 20 showed NDMA in valsartan before July 27, 21 2017? 22 MR. GALLAGHER: Objection. 23 Lack of foundation. 24 A. I don't know.</p>
<p style="text-align: right;">Page 619</p> <p>1 Okay. That patent, if you look 2 through it, it's only talking about, you 3 know, component, you know, like impurity K 4 and L, probably. 5 BY MR. SLATER: 6 Q. Would you be surprised if I was 7 able to show you documentation that your 8 company did chromatography and identified 9 NDMA in valsartan prior to July 27, 2017? 10 Would that surprise you? 11 MR. GALLAGHER: Objection. 12 Argumentative. 13 A. Yeah, I would be surprised if 14 you say, because I don't -- you know, I'm not 15 aware of that. 16 BY MR. SLATER: 17 Q. Would it be surprising to you 18 if we were to show you documents indicating 19 that there were people within your company 20 that had figured out that there were 21 nitrosamines, likely NDMA -- rephrase. Let 22 me rephrase it. 23 I'm going to actually ask you 24 even more directly.</p>	<p style="text-align: right;">Page 621</p> <p>1 BY MR. SLATER: 2 Q. To your knowledge, was anybody 3 in your company disciplined in connection 4 with the valsartan contamination with NDMA? 5 A. I have no knowledge. 6 MR. GALLAGHER: Objection. 7 THE WITNESS: Sorry. 8 MR. GALLAGHER: Lack of 9 foundation, calls for speculation. 10 BY MR. SLATER: 11 Q. For example, did anybody lose 12 their job? 13 MR. GALLAGHER: Same objection. 14 A. I don't know. 15 BY MR. SLATER: 16 Q. Was anybody reassigned? 17 MR. GALLAGHER: Same objection. 18 A. As I said, I don't know. I 19 mean, this is not my job; this is human 20 resources' job. I don't know. 21 MR. SLATER: Let's go, Cheryll, 22 back to Exhibit 319, to the second 23 page, please. 24 Actually, let's -- just to</p>

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1 reorient, just stay there. Thank you.
 2 BY MR. SLATER:
 3 Q. Looking at Exhibit 319, it
 4 starts with a July 5, 2018 e-mail from
 5 Charles Wang to someone named Jim, and we
 6 just went through that e-mail a moment ago.
 7 MR. SLATER: And we can scroll
 8 down to the second page of that
 9 e-mail, please. No, no, that e-mail.
 10 Sorry. Thank you. Go to the bottom
 11 of the page, please. Yes.
 12 Q. Okay. Now, it's actually --
 13 let me ask you this question, actually.
 14 Where -- rephrase.
 15 Where Mr. Wang told Jim that a
 16 friend of his was looking for a consultant in
 17 the United States to help them define their
 18 product at FDA, at that point you were aware
 19 and you had authorized Mr. Wang to find an
 20 independent consultant for you?
 21 MR. GALLAGHER: Are you done?
 22 Objection. Vague.
 23 A. It looks like, yeah, we asked
 24 him probably, you know, yeah, to go ahead and

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1 try to find.
 2 MR. SLATER: Okay. Now let's
 3 go up to the next e-mail, please.
 4 Thank you.
 5 BY MR. SLATER:
 6 Q. In response to Charles Wang's
 7 e-mail on July 5th at 1:50 p.m., Jim
 8 MacDonald, we can see his e-mail, writes back
 9 to Charles.
 10 Do you see that?
 11 A. Yeah, mm-hmm.
 12 Q. He says, "Good to hear from
 13 you.
 14 "I am at the beach with my
 15 family. I'll be back in the office from
 16 Monday and" I will give you -- "and will give
 17 you a call. It will be good to catch up.
 18 "Best regards, Jim."
 19 So that was the response,
 20 correct?
 21 A. Mm-hmm.
 22 MR. SLATER: Okay. Now let's
 23 scroll to the next e-mail, and I think
 24 that the very beginning of that e-mail

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1 is at the bottom of the first page.
 2 Perfect.
 3 Q. Charles Wang then responds on
 4 July 5, 2018 at 10:27 p.m., so this is still
 5 on the same day as the first e-mail.
 6 Do you see that?
 7 A. Yeah, mm-hmm, it's July 5th,
 8 yeah, 2018.
 9 Q. Writes to Jim MacDonald.
 10 A. Mm-hmm.
 11 Q. And he says, "Hi Jim, Nice to
 12 hear from you. Hope everything is going
 13 well."
 14 MR. SLATER: You can scroll
 15 down now, Cheryll, so we have the
 16 whole e-mail.
 17 Q. Okay. I'll start over.
 18 The e-mail reads, "Hi Jim, Nice
 19 to hear from you. Hope everything is going
 20 well.
 21 "Sorry to disturb you during
 22 your vacation. My friend's company will have
 23 a face-to-face meeting with FDA to debit if
 24 they should recall their product in US market

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1 next Thursday and likes to get some advice
 2 from people like you quickly."
 3 Do you see that?
 4 A. Yes.
 5 Q. And that's consistent with what
 6 you had discussed with Mr. Wang, that you
 7 were looking to bring in another consultant
 8 to help prepare for that meeting, correct?
 9 MR. GALLAGHER: Objection to
 10 the extent it mischaracterizes
 11 testimony.
 12 You can answer.
 13 A. As I -- yeah, as I said, yeah,
 14 it looks like, yeah, we, you know, we --
 15 basically we took his recommendation to
 16 looking for, yeah, an expert on the -- you
 17 know, yeah, on that particular, you know,
 18 carcinogenicity area, yeah.
 19 BY MR. SLATER:
 20 Q. And again, as you said earlier,
 21 you had a lot of trust in Mr. Wang,
 22 considered him to be a reliable expert, so
 23 you asked him to go find you the most
 24 qualified person he could find basically,

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1 right?

2 A. Yeah, it looks like.

3 Q. This e-mail continues --

4 rephrase.

5 The e-mail continues, "Not sure

6 if you heard Huahai Pharma Group, one of the

7 largest generic drug company in China with a

8 branch in US (Cranberry, NJ). Li knows their

9 US CEO as well."

10 Do you know who Li is?

11 A. I have no idea.

12 Q. Do you know if that's you

13 that's being referred to?

14 A. Based upon the content, it

15 should not be me.

16 Q. So the -- rephrase.

17 The e-mail continues. "Li

18 knows their US CEO as well. Huahai has a

19 product in US market with the maximum daily

20 dose of 320 milligrams, which recently was

21 found containing high Nitrosodimethylamine

22 (NDMA, not know exactly how much but around

23 30 parts per million)."

24 I want to stop there.

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1 Do you see the reference to

2 30 parts per million?

3 A. Yes.

4 Q. And we've been through the test

5 results already earlier in your deposition.

6 You would agree with me that 30 parts per

7 million is actually on the very low side

8 compared to the ranges of NDMA that was found

9 in the zinc chloride process valsartan,

10 correct?

11 MR. GALLAGHER: Objection.

12 Vague.

13 A. The average, as far as I can

14 remember, is somewhere around like 55 or

15 maybe, you know, between 55 and 60 ppm

16 average.

17 BY MR. SLATER:

18 Q. That's your best recollection?

19 A. Yes.

20 Q. We went through the list, the

21 numbers ranged up as high as 188.1, 165.1,

22 172.3, there were some -- some very high

23 numbers on that chart that we went through

24 the other day, correct?

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1 MR. GALLAGHER: Objection.

2 Vague, and lacks foundation.

3 A. Yes. But these are, you know,

4 very small fractions. We also have very low

5 numbers, like single digit numbers.

6 BY MR. SLATER:

7 Q. Continuing in the e-mail,

8 Charles Wang writes, "Their client in EU" --

9 and that would be the European Union?

10 A. Yeah, it should be.

11 Q. And when they talk about --

12 rephrase.

13 When he speaks about your

14 client in the EU, he's talking about

15 Novartis, right?

16 MR. GALLAGHER: Objection.

17 Lack of foundation.

18 A. I would say probably, but I

19 wouldn't be 100 percent. It probably is

20 Novartis.

21 BY MR. SLATER:

22 Q. It says, "Their client in EU

23 said it should be at 0.3 parts per million

24 based on TD50 calculation."

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1 That was what Novartis said,

2 correct?

3 A. That was Novartis said it at

4 one point, yeah. As I said, you know, some

5 early discussion with Novartis, you know,

6 they were basing the TD50 from a primate, but

7 then the, you know, the threshold would be

8 lower, yeah.

9 But this one, as I said, it

10 looks like based upon the rodent, you know,

11 studies.

12 Q. And the 0.3 that Novartis

13 recommended actually is the number the FDA

14 ended up agreeing on as well, correct?

15 MR. GALLAGHER: Objection.

16 Outside the scope, and lack of

17 foundation.

18 A. I would say eventually. You

19 know, at a very early stage, you know, FDA

20 did take this as an interim spec, and then

21 the, you know, the official allowable intake

22 at that time, you know, as I said, was --

23 should be absent.

24 But then, you know, after, you

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1 know, maybe about a year or so, you know, now
2 FDA basically broadened that to, you know,
3 0.3 ppm.
4 BY MR. SLATER:
5 Q. The e-mail continues. "They
6 would like to know if they can argue to set
7 limit higher based on NDMA is considered a
8 Class 2A carcinogen (limit at threshold of
9 toxicological concern of 1.5 micrograms per
10 day) and the longest duration of human
11 exposure in US will be less than 3 years."
12 Do you see that?
13 A. Yes.
14 Q. And we went through earlier the
15 e-mail where Charles Wang actually told you
16 that NDMA actually should be a class A -- a
17 class -- rephrase.
18 And we went through earlier the
19 e-mail where Charles Wang told you he thought
20 NDMA met the criteria for a Class 1
21 carcinogen. We saw that e-mail a few minutes
22 ago, right?
23 MR. GALLAGHER: Objection.
24 Lack of foundation, and to the extent

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1 it mischaracterizes the document and
2 testimony.
3 A. Yes, we looked through that
4 document. But as I indicated, okay, that's
5 the MSDS, you know, from that particular
6 chemical company, okay.
7 Based upon today's knowledge,
8 you know, if they talking about that
9 classification based upon IARC, you know,
10 that information was incorrect, okay. The
11 IARC categorization as of today is still 2A,
12 Class 2A.
13 BY MR. SLATER:
14 Q. The e-mail continues. "Let me
15 know if your company can help. I will ask
16 them to contact you directly and send you
17 more details.
18 "Thanks a lot for your help and
19 enjoy your vacation. Best, Charles."
20 And that's how that e-mail
21 ended, correct? Do you see that?
22 A. Yes.
23 MR. SLATER: Let's go now,
24 Cheryll, to the next e-mail in the

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1 chain which starts about a third of
2 the way down the first page of this
3 page. Perfect.
4 Q. On July 6, 2018, the next day,
5 at 11:11 a.m., Jim MacDonald responds.
6 Do you see the e-mail?
7 A. Yes.
8 Q. And we now can see where Jim
9 MacDonald comes from, he has a company called
10 Synergy Partners Research & Development
11 Solutions, and he's listed as James S.
12 MacDonald Ph.D, Founding Partner, right?
13 A. Yes.
14 Q. Jim MacDonald writes, "Charles,
15 I'm afraid I can't be of much help in this
16 case particularly on this time scale.
17 "NMDA (or dimethylnitrosamine)
18 is a pretty well-known toxin and animal
19 carcinogen with lots of discussion on
20 permissible levels in drinking water and
21 products. Even though the compound is found
22 in cured meats and some groundwater, the body
23 of evidence on this suggests pretty clearly
24 that this is a likely human carcinogen at

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1 sufficient exposures."
2 Do you see that?
3 A. Yes.
4 Q. And a likely human carcinogen
5 means something that likely causes cancer in
6 humans, that's what that means, correct?
7 A. I think I went through this
8 topic many times. It is a, you know,
9 probable human carcinogen.
10 Q. He continues. "The argument
11 that the company would have to make to keep
12 this product on the market will be very
13 difficult with this profile. I'm not exactly
14 sure where one would begin given the very
15 high levels you think they are seeing."
16 I want to stop there.
17 When he refers to the very high
18 levels, we just saw in the earlier e-mail
19 that he was quoted a level of 30 parts per
20 million in the prior e-mail, correct?
21 MR. GALLAGHER: Objection.
22 Lack of foundation, and calls for
23 speculation.
24 A. Let me read through, okay?

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1 BY MR. SLATER:
 2 Q. Just so you understand my
 3 question, when he refers to the very high
 4 levels you think they are seeing, I had just
 5 shown you in the prior e-mail that Charles
 6 Wang, or Wang, had quoted him 30 parts per
 7 million.
 8 Do you remember that?
 9 MR. GALLAGHER: Objection.
 10 Lack of foundation, and calls for
 11 speculation.
 12 A. Yes, I remember that 30 parts
 13 per million number, yes.
 14 BY MR. SLATER:
 15 Q. So this toxicologist --
 16 rephrase.
 17 So this toxicologist who
 18 Charles Wang was going to on your behalf was
 19 actually telling you that 30 parts per
 20 million were very high levels, and we've
 21 already established the levels were actually
 22 higher, correct?
 23 MR. GALLAGHER: Objection.
 24 Lack of foundation, compound, and

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1 vague.
 2 A. The average value is higher
 3 than 30 ppm. But, you know, there was, you
 4 know, certain numbers of batches that were
 5 below 30 ppm.
 6 BY MR. SLATER:
 7 Q. You told me the average a
 8 moment ago was, your best recollection, was
 9 55 to 60 parts per million, correct?
 10 A. Yes.
 11 Q. And going back to the math that
 12 we did before, if it was 60 parts per million
 13 for a 320-milligram pill, that would be
 14 19,200 nanograms, correct? 60 times 320,
 15 right?
 16 MR. GALLAGHER: Objection.
 17 Calls for speculation and expert
 18 testimony.
 19 Are you asking him to do the
 20 calculation? Do you have a
 21 calculator?
 22 BY MR. SLATER:
 23 Q. You certainly don't -- you can
 24 agree with me or you can check it yourself,

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1 or you can disagree with my math.
 2 A. So your calculation based upon
 3 what, 60 ppm or --
 4 Q. Right, 60 ppm for a
 5 320-milligram pill would be 19,200 nanograms
 6 of NDMA, correct?
 7 MR. GALLAGHER: Same objection.
 8 A. 19,000 -- wait a second. You
 9 said 19,000 -- what is the rest of the
 10 number?
 11 BY MR. SLATER:
 12 Q. 19,200.
 13 A. 200 nanogram.
 14 Q. Right. That's the number,
 15 right?
 16 A. Probably. I mean, you know, I
 17 didn't check myself. But it's probably on
 18 the ball park.
 19 Q. And if it was 60 parts per
 20 million, the average that you told me, and a
 21 160-milligram pill, we do 60 times 160 and
 22 come up with 9,600 nanograms, correct?
 23 MR. GALLAGHER: Same objection.
 24 A. Hold on, let me double-check.

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1 So 60, right, 60 times 320.
 2 Yeah, 19,200 nanogram, yeah,
 3 for the 60 ppm for 320 milligram, yeah.
 4 BY MR. SLATER:
 5 Q. The ultimate limit that the FDA
 6 set was 96 nanograms, correct?
 7 A. Yes.
 8 MR. GALLAGHER: Objection.
 9 Outside the scope.
 10 BY MR. SLATER:
 11 Q. So if we take 19 -- rephrase.
 12 So if we take 60 parts per
 13 million -- rephrase.
 14 If we take a 320-milligram
 15 pill, which would be 19,200 nanograms of
 16 NDMA, and we divide that by 96, it comes to
 17 200.
 18 So that would be 200 times the
 19 limit that the FDA ended up setting, correct?
 20 MR. GALLAGHER: Objection.
 21 Lack of foundation, and outside the
 22 scope, and calls for expert testimony.
 23 A. The calculation, it looks like
 24 it's correct. 19,200 divided by 96 is 200.

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1 BY MR. SLATER:
2 Q. And even for a 160-milligram
3 pill, we'd be talking about 100 times the FDA
4 limit of 96 nanograms, right?
5 MR. GALLAGHER: Objection.
6 Lacks foundation, outside the scope,
7 and calls for expert testimony.
8 A. The calculation seems to be
9 correct.
10 BY MR. SLATER:
11 Q. And that's -- rephrase.
12 And those numbers are based on
13 60 parts per million, which is double the
14 30 parts per million that this toxicologist
15 who was being consulted on your behalf said
16 were already very high levels, correct?
17 MR. GALLAGHER: Objection.
18 Lacks foundation, vague.
19 A. I mean, whatever it says in the
20 e-mail, you know, I mean, it's there.
21 BY MR. SLATER:
22 Q. Reading the e-mail further,
23 Mr. -- rephrase.
24 Reading the e-mail further,

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1 James MacDonald says, "I think the strategy I
2 would probably recommend would be to come up
3 with a CMC plan to remove the contaminant (at
4 least to minimally detectable levels) while
5 they recall the existing product and
6 re-formulate. I expect this is not what they
7 would want to hear but, unless there is a
8 compelling reason to leave this product on
9 the market (e.g.: only product available to
10 treat a serious, life-threatening disease), I
11 would expect the FDA would ask for a recall.
12 I'd be interested to know what happens at the
13 FDA meeting. These things are always very
14 difficult to predict - but this is not a good
15 position for this product in my view.
16 "Hope all is well with you.
17 "Best regards, Jim."
18 Do you see that?
19 A. Yes.
20 Q. And Mr. Wang relayed to you
21 that he had spoken with Jim MacDonald and
22 what the result of that interaction had been
23 after he had heard from Mr. MacDonald,
24 correct?

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1 MR. GALLAGHER: Objection.
2 Lacks foundation.
3 A. I don't remember the details.
4 He probably talked to me verbally, at least.
5 BY MR. SLATER:
6 Q. He certainly would have let you
7 know, hey, I spoke to Jim MacDonald, the guy
8 I thought could help us, unfortunately this
9 is the response I got.
10 He at least would have let you
11 know what happened and what the information
12 was, right?
13 MR. GALLAGHER: Objection.
14 Lacks foundation, calls for
15 speculation.
16 A. I just said I don't remember
17 the detail, okay?
18 And one thing, you know, you
19 know, I think I need to maybe provide, you
20 know, some of the, you know, background,
21 okay?
22 You know, even in this ongoing,
23 right here it's mentioned, you know, this
24 like, you know, upcoming meeting with FDA,

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1 okay, so during that meeting, you know, FDA
2 still asked us to be on hold with regard to
3 our, you know, question whether we should do
4 the recall immediately, okay?
5 So the thing is, you know -- or
6 the fact, you know, indicate at that time FDA
7 still was not sure, you know, obviously, you
8 know, because by considering, you know, the
9 potential drug shortage. So FDA still wasn't
10 sure, you know, what a level or an interim
11 limit should be set, you know, to -- you
12 know, potentially to allow some batch.
13 For example, you know those
14 batch below 30 ppm, you know, still
15 temporarily remain on the market, you know,
16 to address, you know, the potential, you
17 know, drug shortage issue.
18 MR. SLATER: Going now to the
19 top of the page, please.
20 BY MR. SLATER:
21 Q. The next e-mail in this
22 document is July 17, 2018, Charles Wang
23 writes to Jim MacDonald.
24 Do you see that?

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1 A. Mm-hmm.
 2 Q. He says, "Hi Jim. You may have
 3 already seen this," and then he has the link
 4 to Press Announcements.
 5 "It is exactly like you
 6 expected, and I agreed with your call.
 7 "Thanks again for your help.
 8 Keep in touch for the future collaboration
 9 opportunity."
 10 Do you see that?
 11 A. Yes.
 12 Q. And this would have been the
 13 announcement of the recall, correct?
 14 MR. GALLAGHER: Objection.
 15 Lacks foundation.
 16 A. That's July 17th.
 17 So can we go down? Okay.
 18 So the previous one was the
 19 July 6th. So whether this is related to
 20 recall, you know, we can take a look, you
 21 know.
 22 Can we, you know, take a look
 23 of this announcement?
 24 ///

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1 BY MR. SLATER:
 2 Q. I'm just asking if you agree
 3 with me that he would have been talking about
 4 the recall at that point, on July 17, 2018.
 5 MR. GALLAGHER: Objection.
 6 Lacks foundation.
 7 A. I mean, eventually FDA, yeah,
 8 basically agree, you know, with us, you know,
 9 at that time, you know. They, you know,
 10 allow us to, you know, to initiate the
 11 recall, you know, for those batches, you
 12 know, impacted. Yeah.
 13 But I'm not sure whether, you
 14 know, if this particular July 17th. But it
 15 looks like, but, you know -- but essentially,
 16 as I said, that during the -- you know, that
 17 upcoming meeting, you know, a teleconference
 18 meeting with FDA, you know, FDA at the time
 19 still asked us to hold on the recall.
 20 BY MR. SLATER:
 21 Q. Where -- rephrase.
 22 Charles Wang, as we can see in
 23 this e-mail, told Jim MacDonald, "I agreed
 24 with your call."

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1 MR. GALLAGHER: Objection.
 2 Lacks foundation.
 3 BY MR. SLATER:
 4 Q. Did Charles Wang tell you that
 5 he agreed with Jim MacDonald's call on what
 6 should happen here?
 7 MR. GALLAGHER: Objection.
 8 Lacks foundation.
 9 A. So the e-mail, you know, yeah,
 10 says whatever, yeah, he says. I mean, as I
 11 told you, you know, from the very beginning,
 12 you know, after, you know, you know, you
 13 know, you know, we determined the root cause,
 14 you know, we determined -- you know, we
 15 developed a method and we, you know,
 16 determined the range or the average of the
 17 contents, as I said, we immediately, you
 18 know, approach FDA, ask whether we should do,
 19 you know, immediate recall, you know, as I
 20 said.
 21 But it looks like, you know,
 22 it's probably, based upon the contents, you
 23 know, the likely scenario would be, yeah, by
 24 July 17th FDA made this announcement, and

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1 also we also received, you know, FDA's
 2 instruction, you know, to start recall, as we
 3 have been asking FDA, you know, you know,
 4 whether we should do, you know, immediately
 5 or as soon as, you know, it should be done.
 6 MR. SLATER: Cheryll, if you
 7 could scroll down a little bit more,
 8 please. Perfect.
 9 BY MR. SLATER:
 10 Q. I want to go back to the e-mail
 11 from July 6th where it's documented that
 12 Dr. MacDonald told Charles Wang that the body
 13 of evidence suggests pretty clearly that this
 14 is a likely human carcinogen at sufficient
 15 exposures. Do you recall we talked about
 16 that a few moments ago?
 17 A. Yes.
 18 Q. Charles Wang told you the same
 19 thing, right?
 20 MR. GALLAGHER: Objection.
 21 Lacks foundation, and I'm going to
 22 object to outside the scope.
 23 Adam, I've let you ask
 24 questions about this --

<p style="text-align: right;">Page 646</p> <p>1 MR. SLATER: I don't know why 2 you're saying this, Patrick. This is 3 ZHP's evaluation of knowledge of the 4 health risks of nitrosamines, 5 Topic 36. 6 MR. GALLAGHER: Nobody from -- 7 nobody from ZHP is on this e-mail. 8 Nobody from ZHP is on this e-mail. He 9 said he doesn't recall talking to him. 10 MR. SLATER: Are you going to 11 testify now? Relax. Are you going to 12 testify now? 13 MR. GALLAGHER: No, I'm 14 objecting it's outside the scope. You 15 told -- you just said ZHP's knowledge. 16 Nobody from ZHP is on this e-mail. 17 MR. SLATER: Are you testifying 18 now -- 19 MR. GALLAGHER: You're trying 20 to put words in Dr. Wang's mouth of 21 what he told Dr. Li. He said he 22 doesn't recall. I'm just objecting 23 outside the scope. Ask your 24 questions.</p>	<p style="text-align: right;">Page 648</p> <p>1 IARC, you know, you know, classification to 2 be, you know, 2A, you know, basically means, 3 you know, you know, it's a potential or 4 probable, you know, to human based upon, you 5 know, animal, you know, you know, studies. 6 BY MR. SLATER: 7 Q. Did you or anybody from your 8 company ever tell the FDA that a toxicologist 9 who was hired by your company advised you 10 that NDMA was a likely human carcinogen? 11 MR. GALLAGHER: Objection. 12 Outside the scope, and calls for 13 speculation. 14 A. I don't remember, you know -- 15 MR. GALLAGHER: And lack of 16 foundation. 17 MR. SLATER: Just bear with me 18 for a second. I think I misplaced a 19 document. Sorry, everyone, but I'm a 20 little confused. 21 Okay. I got it. Okay. 22 We can take this one down. And 23 let's go to -- the last one was 319, 24 right? Let's go to Exhibit 320, which</p>
<p style="text-align: right;">Page 647</p> <p>1 MR. SLATER: Would you like to 2 testify? We could place you under 3 oath if you want? I mean, you're 4 literally -- you realize how far over 5 the line what you just did is. Please 6 don't do that again. I'd really 7 appreciate it. 8 BY MR. SLATER: 9 Q. Did Charles Wang tell you that 10 it was clear to him that NDMA was a likely 11 human carcinogen at sufficient exposures when 12 you were consulting with him? 13 MR. GALLAGHER: Objection. 14 Lack of foundation. 15 A. As I said, I don't remember, 16 you know, such details, okay. But based 17 upon, you know, the e-mail communication with 18 him, yeah, he indicated, yeah, it's a likely, 19 you know, human carcinogen, okay, based upon, 20 you know, the results from animal studies. 21 Right. It's likely, you know, it's a 22 probable, you know, it's -- you know, it's 23 the same meaning. 24 I mean, just like in, you know,</p>	<p style="text-align: right;">Page 649</p> <p>1 starts with CHARLESWANG000164. 2 (Whereupon, Exhibit Number 3 ZHP-320 was marked for 4 identification.) 5 MR. SLATER: And what I'd like 6 to do is go to page -- the Bates 7 number is 179. Go to the very top. I 8 just really want to go to the very top 9 of the page, actually. 10 BY MR. SLATER: 11 Q. Do you see at the top it says, 12 "WeChat communication with Min Li and Jun Du, 13 July 8, 2018"? 14 A. Okay. 15 Q. Do you see that? 16 A. Mm-hmm. 17 Q. And do you recall that you 18 communicated through WeChat with Charles Wang 19 and -- or Charles Wang and Jun Du? 20 A. I don't recall the details. 21 Q. Why was Jun Du involved in any 22 of your interactions with Charles Wang? 23 A. Why? I mean he's the -- you 24 know, first of all, he's the executive vice</p>

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1 president of the company, and also he's the
 2 head of Huahai in the US and also, you know,
 3 the Princeton Pharma.
 4 Q. Did you tell Jun Du the
 5 feedback you got from Charles Wang after he
 6 had communicated with Jim MacDonald in early
 7 July 2018?
 8 MR. GALLAGHER: Objection.
 9 Vague, and lack of foundation.
 10 A. I'm sorry, could you repeat the
 11 question?
 12 BY MR. SLATER:
 13 Q. Sure.
 14 Did you tell Jun Du the
 15 feedback you got from Charles Wang after he
 16 had communicated with Jim MacDonald in early
 17 July of 2018?
 18 A. I don't remember -- sorry.
 19 MR. GALLAGHER: Objection.
 20 Lack of foundation.
 21 A. I mean, as I said, I don't
 22 remember, you know, such details, but at a
 23 such -- you know, at a certain point, you
 24 know, he came to know.

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1 BY MR. SLATER:
 2 Q. At some point you told him?
 3 A. I don't remember whether I
 4 told -- told him or Charles Wang told him. I
 5 just don't remember, you know, you know, the
 6 details.
 7 Q. Now, what I want to do is go to
 8 the very first page of this document now, the
 9 Bates number 164. Let's go back up to the
 10 top.
 11 And this was a draft report
 12 that Charles Wang provided.
 13 MR. SLATER: Cheryll, if you
 14 could scroll down to the bottom half
 15 of the page just so we can show that.
 16 Q. And you recall Charles Wang
 17 provided some potential draft reports for you
 18 about safety assessments for NDMA?
 19 MR. GALLAGHER: Objection.
 20 Lack of foundation.
 21 A. There are probably some draft,
 22 yes.
 23 BY MR. SLATER:
 24 Q. What I'd like to do now is --

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1 MR. SLATER: Cheryll, can you
 2 go to page 10 of this? The Bates
 3 number is 173, please.
 4 Q. There's a table that we see on
 5 this page, and it says, "Table 1: Reasonable
 6 Worst-Case Estimates of Daily Intake of NDMA
 7 by the General Population in the Sample
 8 Country."
 9 Do you see that?
 10 A. Yes.
 11 Q. Do you know where that table
 12 came from?
 13 MR. GALLAGHER: Objection.
 14 Lack of foundation.
 15 A. Right now I don't, just don't
 16 remember the details.
 17 BY MR. SLATER:
 18 Q. To the ex -- well, rephrase.
 19 Or withdrawn actually.
 20 Okay. Let's -- just so that
 21 you can be familiar with this table, you see
 22 that it talks about how people can be exposed
 23 to NDMA and -- during the day, and it lists
 24 on the left-hand column things like air,

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1 water, food, indoor air, groundwater, beer,
 2 and shampoo.
 3 Do you see that?
 4 MR. GALLAGHER: Objection.
 5 Vague, and lack of foundation.
 6 A. It is listed there.
 7 MR. SLATER: Okay. Let's take
 8 that down now and go to Exhibit 210.
 9 Give me a second. You know, I
 10 apologize, Cheryll, can you go back to
 11 the prior exhibit, please? I'm sorry
 12 to make you go back, it's Exhibit 320.
 13 If you could, go back, go back
 14 to page Bates number 182, please.
 15 It's page 19 of the report, of the
 16 draft.
 17 BY MR. SLATER:
 18 Q. This is at the end of that
 19 draft report that Charles Wang provided. Do
 20 you see this, he provided a biography?
 21 A. Yes.
 22 MR. GALLAGHER: Objection.
 23 Lack of foundation, and
 24 mischaracterizes testimony.

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1 MR. SLATER: What's the lack of
 2 foundation? It's a document you
 3 produced to us.
 4 MR. GALLAGHER: The document
 5 Charles -- it came from Charles Wang.
 6 You haven't established with the
 7 witness or what --
 8 MR. SLATER: What haven't I
 9 established? I'm sorry.
 10 MR. GALLAGHER: You don't know
 11 what the document is. It's a document
 12 that was produced from Charles Wang.
 13 MR. SLATER: We already
 14 established it's a draft that was --
 15 of a report that was provided dated
 16 June 15, 2018. We already went over
 17 that with the witness. We already
 18 established that's what they were
 19 getting from Charles Wang.
 20 MR. GALLAGHER: I don't think
 21 you established where it came -- it's
 22 a document that was produced from
 23 Charles Wang, and it's dated June 15,
 24 2018. I don't think you've

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1 established anything else about this
 2 document.
 3 MR. SLATER: Okay.
 4 BY MR. SLATER:
 5 Q. Looking now at the biography
 6 that Charles Wang put in there, I just went
 7 through this for a moment, and he gives some
 8 of his background and he says that, around
 9 the middle, he was the "Vice President of
 10 Drug Safety and Regulatory Affairs at Hua
 11 Medicine, Limited, a US VC funded
 12 biopharmaceutical company in China."
 13 A. I'm sorry, where that word?
 14 Q. Right in the middle of the
 15 biography.
 16 A. Okay. Dr. Wang, okay. Was the
 17 vice president. Let me read through.
 18 (Witness reviewing document.)
 19 A. Yeah, okay. Yeah.
 20 Q. Then it says -- rephrase.
 21 It says that he was "Director
 22 of Toxicology at Johnson & Johnson PRD,"
 23 whatever that firm is, and "Senior Scientist
 24 at Novartis Pharmaceutical Corp. in the

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1 United States."
 2 Do you see that?
 3 A. Yes.
 4 Q. Do you know why this doesn't
 5 list the fact that he was currently working
 6 at GlaxoSmithKline?
 7 MR. GALLAGHER: Objection.
 8 Calls for speculation.
 9 A. I have no idea.
 10 MR. SLATER: All right. Now we
 11 can go back to the other exhibit.
 12 Thank you, Cheryll. Exhibit 210.
 13 You know what? I lied again.
 14 I'm sorry. If you could go back to
 15 page 10 again of the other document,
 16 I'm sorry. I'm trying to make life
 17 difficult tonight for you.
 18 BY MR. SLATER:
 19 Q. Just above the table that we
 20 were discussing a moment ago, there's a line
 21 that says. "The worst-case estimation of
 22 daily intake of NDMA from different sources
 23 by general population at different age are
 24 listed below." And it says "[66]."

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1 And what I'd like to do, if we
 2 could. Is go to the references at the end of
 3 the report, and it's page 14, the Bates
 4 number is 177, to see what reference 66 is
 5 and where that table came from.
 6 And you see reference 66?
 7 A. Yes.
 8 Q. It's a citation from the
 9 "Concise International Chemical Assessment
 10 Document 38, N-nitroso dimethylamine," which
 11 is NDMA, and it gives the authors' names, and
 12 it says it was from the World Health
 13 Organization in Geneva 2002, page 13.
 14 Do you see that?
 15 A. Yes.
 16 MR. SLATER: Let's try this for
 17 the fourth time. Can we please go to
 18 Exhibit 210 now. Exhibit 210 is the
 19 Deviation Investigation Report.
 20 And let's scroll down to make
 21 sure we have exactly which it is and
 22 what the date is. Perfect.
 23 Q. And it's dated -- it says
 24 "Preparation Date: November 5, 2018," and

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1 then on the next page there's a list of
2 signatures, report, review and approval,
3 showing this was signed and finalized,
4 correct?
5 A. Yes.
6 Q. And the deviation investigation
7 report, this is a document that's laying out,
8 among other things, the root cause and the
9 significance of the contamination, correct?
10 MR. GALLAGHER: Objection to
11 the extent it mischaracterizes the
12 document.
13 A. It investigate the root cause
14 or the likely root cause.
15 BY MR. SLATER:
16 Q. This is -- rephrase.
17 This is a document that's
18 supposed to be fully accurate, right?
19 A. Based upon the knowledge at the
20 time.
21 Q. This document is supposed to be
22 fair and balanced in terms of providing
23 information, right?
24 MR. GALLAGHER: Objection.

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1 Vague.
2 A. As I said, to the best
3 knowledge available at that time.
4 BY MR. SLATER:
5 Q. Would you agree that this
6 document should be an honest, scientifically
7 rigorous document in terms of its analysis?
8 MR. GALLAGHER: Objection.
9 Vague.
10 A. Again, I said, you know, it's
11 to the best knowledge, you know, of the
12 authors at the time.
13 MR. SLATER: Cheryll, let's go,
14 if we could, to page 10 of 236,
15 please, the very top.
16 By the way, everyone, I have
17 zero idea about time, so I don't know
18 where you're at. I'm about to start
19 in on this document, so now would
20 probably be a good break time if we're
21 at that point.
22 MR. GALLAGHER: I think we're
23 just a little bit over an hour, so
24 I'll leave it to you.

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1 MR. SLATER: Let's do that,
2 because otherwise we'll break up in
3 the middle.
4 MR. GALLAGHER: Okay.
5 MR. SLATER: So let's take a
6 break.
7 How long do you want?
8 MR. GALLAGHER: Dr. Li, how
9 long would you like for a break?
10 THE WITNESS: 15 minutes. Or
11 maybe we come back at, what, 10:25?
12 MR. GALLAGHER: Sounds great.
13 MR. SLATER: Whatever you want.
14 Sounds good.
15 THE VIDEOGRAPHER: The time
16 right now is 10:09 a.m. We're off the
17 record.
18 (Whereupon, a recess was
19 taken.)
20 THE VIDEOGRAPHER: The time
21 right now is 10:27 a.m. We're back on
22 the record.
23 BY MR. SLATER:
24 Q. Looking here at the deviation

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1 investigation report, this is Section 3.1.2,
2 titled "NDMA Physiochemical Characteristics
3 and Toxicological Evaluation of NDMA."
4 Do you see that?
5 A. Yes.
6 Q. The toxicological evaluation
7 would be the part of the report where you got
8 consulting services from Dr. Wang, right?
9 A. Yeah, it should be.
10 MR. SLATER: And let's turn, if
11 we could, to the next page. Scroll up
12 a little bit. A little more. Thank
13 you.
14 Q. Looking now at page 11 of this
15 report, you can see that there's a citation
16 to something that was stated in the report to
17 the Concise International Chemical Assessment
18 Document 38 on NDMA, which we just saw before
19 was cited in Dr. Wang's report, correct?
20 A. Yes.
21 Q. And one thing to be clear --
22 rephrase.
23 To be clear, ZHP would only
24 cite scientifically reliable literature in

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1 this report, correct?

2 A. As I said, again, you know,

3 based upon the best knowledge, and also, like

4 you said, you know, this data is likely, you

5 know, yeah, from, yeah, Dr. Wang's report,

6 yes.

7 Q. Would ZHP cite literature or

8 articles in this report that it did not

9 believe was scientifically reliable?

10 A. It shouldn't.

11 MR. SLATER: Let's turn to the

12 next page, page 12 of this report.

13 Q. We can actually see that that

14 table that was cited in Dr. Wang's report and

15 cited to that World Health Organization study

16 is also actually found right here in the

17 deviation investigation report, correct?

18 A. Yes.

19 MR. SLATER: Let's scroll down

20 a little bit.

21 Q. There's a section titled

22 "Animal Toxicity Studies," and it says in

23 part --

24 MR. SLATER: Scroll down a

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1 little more, actually. Perfect.

2 Q. Under the "Animal Toxicity

3 Studies" section, it says in part in that

4 second paragraph, "Carcinogenicity studies in

5 animals demonstrated that NDMA is

6 carcinogenic. However, no evidence is

7 available to confirm that NDMA is

8 carcinogenic in humans. Nevertheless, NDMA

9 is considered a probable human carcinogen

10 based on projection from the animal studies."

11 And that's the -- that's what

12 your company stated in this deviation

13 investigation report, correct?

14 A. Yes.

15 Q. Now, we had talked a moment ago

16 that the table up above came from the World

17 Health Organization study, the Concise

18 International Chemical Assessment document

19 regarding NDMA.

20 Do you recall that?

21 A. Yes.

22 Q. And what we can do now is we

23 can take this document down, and we can go --

24 MR. SLATER: I guess -- I don't

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1 know what the next exhibit would be.

2 Is it 321?

3 THE STENOGRAPHER: Yes, it is.

4 MR. SLATER: Okay. Let's go,

5 Cheryll, to Exhibit 321, the actual

6 Concise International Chemical

7 Assessment Document 38 regarding NDMA

8 that's cited here in the deviation

9 investigation report. Thank you.

10 (Whereupon, Exhibit Number

11 ZHP-321 was marked for

12 identification.)

13 BY MR. SLATER:

14 Q. And you can see that that's the

15 title.

16 MR. SLATER: And if you can

17 scroll down, Cheryll, just to confirm

18 the date of it at the bottom, please.

19 Perfect.

20 Q. You can see the "World Health

21 Organization, Geneva, 2002," correct?

22 A. Yes.

23 Q. Let's first, just to be sure --

24 rephrase.

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1 MR. SLATER: Turn, if you

2 could, Cheryll, to page 1. It's a

3 couple pages ahead.

4 And you see there's a section

5 that says -- rephrase. Stop, stop,

6 stop, stop.

7 Q. You see it says "Procedures,"

8 correct?

9 A. Yes.

10 MR. SLATER: Scroll down,

11 please, Cheryll, so we capture the

12 last two paragraphs on this section.

13 Perfect.

14 Q. You can see that the second

15 paragraph under the Procedures talks about

16 how the first draft was prepared. It says,

17 "The first draft is based on existing

18 national, regional, or international review."

19 And there's more information.

20 Do you see that?

21 A. Yes.

22 Q. And then the next paragraph

23 says, "The draft is then sent to an

24 international peer review by scientists known

<p>Page 666</p> <p>1 for their particular expertise and by 2 scientists selected from an international 3 roster compiled by IPCS through 4 recommendations from IPCS national Contact 5 Points and from IPCS" participation -- 6 "participating institutions." 7 And peer review is an important 8 thing in scientific literature because that's 9 one of the important stamps of reliability 10 for scientific literature, correct? 11 A. Yes. 12 MR. SLATER: Let's go now, 13 Cheryll, if we could, to page 13. 13. 14 The very top. Perfect. 15 Q. We can see here on page 13 that 16 the table that we've been talking about that 17 was copied into Dr. Wang's report and into 18 the deviation investigation report is found 19 in this article as cited. 20 Do you see that? 21 A. Yes. 22 MR. SLATER: Let's go now, 23 Cheryll, to page 26, if we could. And 24 if you could go down to the last part</p> <p>Page 667</p> <p>1 of that page, Section 12, there's a 2 little paragraph there. On this page, 3 just go to the bottom of the page. 4 Oh no. I'm getting a feeling 5 like a frozen computer issue is 6 happening. "Frozen." I just got a 7 text from Cheryll, "Frozen." 8 Could we go off for a moment 9 just while she fixes her issue, 10 please? 11 MR. GALLAGHER: Sure. 12 THE VIDEOGRAPHER: The time 13 right now is 10:35 a.m. We're now off 14 the record. 15 (Whereupon, a recess was 16 taken.) 17 THE VIDEOGRAPHER: The time 18 right now is 10:40 a.m. We're back on 19 the record. 20 BY MR. SLATER: 21 Q. I want to go through the 22 document a little bit, this article. First 23 we'll start in Section 12 titled "Previous 24 Evaluations By International Bodies."</p>	<p>Page 668</p> <p>1 And this states, "NDMA has been 2 classified by the International Agency for 3 Research on Cancer (IARC, 1987) as a 4 'probable human carcinogen (Group 2A),' based 5 upon sufficient evidence of a carcinogenic 6 effect in experimental animal species and the 7 demonstrated similarities in its metabolism 8 by human and rodent tissues." 9 Do you see that? 10 A. Yes. 11 Q. And in terms of the risks to 12 humans as compared to animals, you certainly 13 don't disagree that there are similarities in 14 the metabolism of humans and rodents as 15 stated here, you certainly don't disagree 16 with that, right? 17 A. Whatever that statement says. 18 Q. Let's go now to page 16. 19 Page 16, heading 8.4, it says 20 "Carcinogenicity," and again that's whether 21 something causes cancer, right? 22 A. Yes. 23 Q. And if you go a little further 24 down actually, let's go to Section 8.5,</p> <p>Page 669</p> <p>1 perfect, Section 8.5 is "Genotoxicity and 2 related end-points." 3 And genotoxicity is where -- 4 well, you can explain it. Tell me, what's 5 your understanding of genotoxicity? 6 A. Any chemical substances, you 7 know, where they chemically react with DNA. 8 Q. And this states in numerous -- 9 well, rephrase. Let me just take a step 10 back. 11 NDMA is a genotoxic substance, 12 correct? 13 MR. GALLAGHER: Objection. 14 Vague, and calls for expert testimony. 15 A. It is. 16 BY MR. SLATER: 17 Q. NDEA is also a genotoxic 18 substance, correct? 19 MR. GALLAGHER: Same 20 objections. 21 A. Yes. 22 BY MR. SLATER: 23 Q. This section states, "In 24 numerous studies conducted in vitro in</p>
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1 bacterial and mammalian cells, there has been
2 overwhelming evidence that NDMA is mutagenic
3 and clastogenic (reviewed in IARC, 1978;
4 ATSDR, 1989). Increased frequency of gene
5 mutations, chromosomal damage, sister
6 chromatid exchange, and unscheduled DNA
7 synthesis have been observed in a wide
8 variety of cell types, in assays conducted in
9 the presence or absence of metabolic
10 activation. Positive results have been
11 observed in human as well as rodent cells."
12 Do you see that?
13 A. Yes, that's what it said.
14 Q. Then it says, "Similarly, clear
15 evidence of genetic effects has also been
16 observed in in vivo studies," correct?
17 A. In vivo studies, mm-hmm.
18 MR. SLATER: Let's go now, if
19 we could, Cheryll, to page 21. This
20 is Section 9, "Effects on Humans."
21 And if you could scroll down, Cheryll,
22 to the second paragraph under there.
23 Q. The second paragraph starts
24 out, "Relevant epidemiological studies

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1 include case-control investigations in which
2 the potential risks of cancer of the
3 stomach," and I'm going to skip the citation
4 names for now, "upper digestive tract, and
5 lung associated with the ingestion of NDMA
6 have been assessed."
7 So they're citing to studies
8 that have looked at whether or not there's a
9 risk to humans from NDMA, correct?
10 A. It looks like.
11 MR. SLATER: Let's go now to
12 the other -- the second column at the
13 top, please. Let's get that top half
14 of the page. Perfect.
15 Q. Continuing this section
16 regarding effects on humans of NDMA, it says,
17 "In three of four case-control studies, there
18 was a positive relationship with evidence of
19 exposure-response for the intake of NDMA and
20 gastric cancer."
21 You see that citations, there's
22 three articles cited right there?
23 A. Yes.
24 Q. Then if we go a little further

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1 down, it says, "In two case-control studies
2 in which matching or control for confounders
3 was rather more extensive than that for the
4 investigations of gastric cancer mentioned
5 above, three [sic] were clear
6 exposure-response relationships for NDMA and
7 lung cancer."
8 Do you see that?
9 A. Yes.
10 Q. And what they're talking about
11 here with this -- this -- rephrase.
12 And what they're talking about
13 here is that there are epidemiologic studies
14 that have been done showing that there is a
15 clear relationship between NDMA and humans
16 developing certain cancers, correct? That's
17 what they're talking about?
18 MR. GALLAGHER: Objection.
19 Foundation, calls for expert
20 testimony.
21 A. Well, they're talking about
22 some, like you said, epidemiology, you know,
23 studies.
24 ///

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1 BY MR. SLATER:
2 Q. It continues, "In almost all
3 studies, associations between the cancers of
4 interest and nitrate, nitrite, and NDMA were
5 examined; results were relatively consistent
6 in this regard, with there being an
7 association with cancer most commonly with
8 NDMA"; and then it says, "results for nitrite
9 were mixed, and there was an inverse
10 association with nitrate."
11 Do you see what I just read?
12 A. Yes.
13 Q. And -- rephrase.
14 When they talk about an
15 association with cancer most commonly seen
16 with NDMA, they're talking about cancer in
17 human beings, correct?
18 MR. GALLAGHER: Objection.
19 Calls for expert testimony, and
20 outside the scope.
21 A. I'm not sure they are purely
22 talking about, you know, with cancer in
23 human, just based upon, you know, this
24 statement.

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1 BY MR. SLATER:
2 Q. This section is "Effects on
3 Humans," and it's relating the results of
4 epidemiologic studies.
5 Those would be studies of
6 cancer in human beings, correct?
7 MR. GALLAGHER: Objection.
8 Calls for speculation, and lack of
9 foundation.
10 A. Let me read through that part,
11 okay?
12 BY MR. SLATER:
13 Q. You understand the question is,
14 these are epidemiologic studies regarding
15 causation of cancer in human beings, and I'm
16 just asking you to confirm this has to do
17 with humans.
18 MR. GALLAGHER: Lack of
19 foundation, and outside the scope.
20 A. Well, these studies' subject,
21 yes, was tried to evaluate.
22 BY MR. SLATER:
23 Q. Cancer in human beings due to
24 NDMA, that's what this is looking at,

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1 correct?
2 A. Looks like.
3 MR. SLATER: Let's go now, if
4 we could, to the next page, please,
5 page 22 of this article.
6 Q. In the top left --
7 MR. SLATER: Perfect, Cheryl.
8 Thank you.
9 Q. In the top left, the first full
10 paragraph it says, "There appears to be no
11 qualitative difference between rodents and
12 humans in the formation of DNA adducts
13 following exposure to NDMA."
14 Do you remember we went through
15 a study last night that actually talked about
16 studying the adducts that are caused -- the
17 DNA adducts caused by exposure to NDMA?
18 Do you recall we talked about
19 that last night?
20 A. Yes.
21 Q. And that's a very important
22 part of a mutagenic, genotoxic substance is
23 the formation of DNA adducts as part of the
24 process whereby somebody will eventually

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1 develop cancer, correct?
2 MR. GALLAGHER: Objection.
3 Vague, calls for expert testimony.
4 A. I think it does ask for
5 speculation. Okay. Based upon my limited
6 knowledge, you know, once, you know, a piece
7 of DNA, for example, was alkylated, different
8 species, you know, they may have different
9 defense system, okay? They can dealkylate.
10 So, you know, it still -- you
11 know, you just make -- you cannot be
12 100 percent sure, okay, just simply because
13 of the presence of alkylated DNA, you know.
14 Because otherwise, you know, if what you're
15 saying, you know, is true, then there will be
16 no difference between, you know, you know,
17 the mutagenicity with carcinogenicity, okay?
18 These are the two different levels. Okay.
19 So you were equating those two
20 things, you know, you know, to be the same
21 meaning, so I don't think that that's
22 accurate.
23 BY MR. SLATER:
24 Q. Mutagenicity is the ability to

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1 actually damage the DNA, leading to cancer,
2 right?
3 A. That's just a potential.
4 MR. GALLAGHER: Objection.
5 Calls for expert testimony.
6 BY MR. SLATER:
7 Q. I'm asking you what
8 "mutagenicity" means. That means that
9 something damages DNA, leading to cancer,
10 correct?
11 MR. GALLAGHER: Objection.
12 Calls for expert testimony.
13 A. As I said, you know, your
14 statement is not accurate, okay. That's just
15 a potential -- you know, you know, a
16 potential source leading to. Because
17 otherwise, why people or why scientists will
18 have two different terms?
19 And also, you know, it's very
20 clear, you know, you know, mutagenicity, you
21 know, can but do not necessarily are
22 carcinogenetic. I mean, you can -- you know,
23 you can find it, like, in some documents,
24 maybe even in M7 itself or some related

<p style="text-align: right;">Page 678</p> <p>1 document.</p> <p>2 BY MR. SLATER:</p> <p>3 Q. Do you know what a mutagenic,</p> <p>4 genotoxic substance is?</p> <p>5 A. I mean, do I know some chemical</p> <p>6 part of being mutagenic?</p> <p>7 Q. Do you know what those terms</p> <p>8 mean?</p> <p>9 A. As I said, yeah. You know, as</p> <p>10 I said, "mutagenic" means, you know, a</p> <p>11 chemical substance will chemically react with</p> <p>12 DNA.</p> <p>13 But whether or not, you know,</p> <p>14 that reactivity or formation of the DNA</p> <p>15 adduct either will lead to, you know, cancer,</p> <p>16 you know, that's another -- you know, another</p> <p>17 question. Okay. It may or it may not, you</p> <p>18 know.</p> <p>19 So you trying to equating them,</p> <p>20 you know, you know, you know, the</p> <p>21 mutagenicity, you're trying to equating them,</p> <p>22 you know, to carcinogenicity, you know. This</p> <p>23 is -- you know, this is not correct.</p> <p>24 Q. I'm actually just -- okay.</p>	<p style="text-align: right;">Page 680</p> <p>1 it gives a citation.</p> <p>2 Then it says, "Using an</p> <p>3 immunohistochemical technique, Parsa et al.</p> <p>4 (1987) detected the formation of</p> <p>5 O6-methylguanine in human pancreatic explants</p> <p>6 incubated in vitro with NDMA."</p> <p>7 So those are some of the</p> <p>8 sources cited for the proposition at the</p> <p>9 beginning of the paragraph indicating there</p> <p>10 appears to be no qualitative difference</p> <p>11 between rodents and humans in the formation</p> <p>12 of DNA adducts following exposure to DNA --</p> <p>13 NDMA.</p> <p>14 That's what it's stating,</p> <p>15 correct?</p> <p>16 MR. GALLAGHER: Objection to</p> <p>17 the extent it mischaracterizes the</p> <p>18 document.</p> <p>19 A. Just by reading through, you</p> <p>20 know, you know, you know, this particular</p> <p>21 sentence, okay, it seems like -- because when</p> <p>22 you're talking about, you know, poisoning or</p> <p>23 NDMA poisoning, you know, based upon my</p> <p>24 limited knowledge, okay, it seems to be</p>
<p style="text-align: right;">Page 679</p> <p>1 I'll withdraw that.</p> <p>2 When I said "I'll withdraw</p> <p>3 that," it was the first two words I said</p> <p>4 almost starting this question. Okay?</p> <p>5 Continuing to read this, it</p> <p>6 says, "In a case of suspected NDMA poisoning</p> <p>7 in a human male, methylation of liver DNA was</p> <p>8 evident at both the N7 and O6 positions</p> <p>9 of" --</p> <p>10 A. I'm sorry. I'm sorry. Hold</p> <p>11 on. I don't see -- I'm not seeing, you know,</p> <p>12 the paragraph that you're reading.</p> <p>13 Q. Sure.</p> <p>14 I'm in the left column, the</p> <p>15 first full paragraph. We just went through</p> <p>16 the first sentence. Now I'm at the second</p> <p>17 sentence.</p> <p>18 A. The second -- oh, okay, yeah.</p> <p>19 Q. The second sentence --</p> <p>20 rephrase.</p> <p>21 This paragraph continues, "In a</p> <p>22 case of suspected NDMA poisoning in a human</p> <p>23 male, methylation of liver DNA was evident at</p> <p>24 both the N7 and O6 positions of guanine," and</p>	<p style="text-align: right;">Page 681</p> <p>1 related to acute, you know, poisoning, which</p> <p>2 means, you know, will be extremely high, you</p> <p>3 know, levels of, you know, NDMA, okay.</p> <p>4 So the acute poisoning, it</p> <p>5 would be different, you know, in terms of the</p> <p>6 mechanism, you know, for the -- you know, for</p> <p>7 the cause or potential, you know, you know,</p> <p>8 you know, you know, cause to cancer. You</p> <p>9 know, I think they are two different</p> <p>10 mechanisms, okay.</p> <p>11 So, again, you know, as I said,</p> <p>12 you know, you know, the DNA adducts, you</p> <p>13 know, you know, you know, alone, you know,</p> <p>14 will not necessarily, you know, leading to,</p> <p>15 you know, cancer.</p> <p>16 But, again, you know, I think</p> <p>17 that this will need a -- you know, a</p> <p>18 professional, you know, toxicologist, you</p> <p>19 know, to give, you know, more precise and</p> <p>20 accurate, you know, evaluation or statement.</p> <p>21 BY MR. SLATER:</p> <p>22 Q. To be clear as we continue to</p> <p>23 read through this article, this was an</p> <p>24 article that was cited in ZHP's deviation</p>

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1 investigation report dated November 5, 2018,
2 correct?
3 A. We cited particularly that
4 table. Very specific.
5 Q. You cited this paper, and you
6 cited it for that table that we looked at,
7 right? The table about various substances
8 and what may -- what may be the NDMA levels,
9 remember?
10 That was why it was cited,
11 right?
12 A. Yeah, yeah. The very reason we
13 cited it, because of the origin of this
14 table.
15 Q. What you didn't do is cite any
16 of these other things I've been reading so
17 far about, for example, the epidemiologic
18 studies relating to humans developing cancer
19 as a result of exposure to NDMA.
20 Those -- that part of the
21 article wasn't cited in your deviation
22 investigation report on the toxicological
23 effects of having NDMA in your valsartan,
24 right?

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1 MR. GALLAGHER: Objection.
2 Foundation, and to the extent it
3 mischaracterizes the document or --
4 A. Look. In that deviation
5 report, okay, we clearly indicated, okay,
6 NDMA, you know, you know, I think is
7 carcinogenic to animals, okay. It's a
8 probable, you know, carcinogenic to human.
9 Okay.
10 So everything, you know, that
11 you presented here, right, do not change the
12 fact, okay. Even as of today NDMA is still
13 being characterized as a Class 2A compound,
14 which -- you know, which means, you know, as
15 I said, it's carcinogenic to animal, and it's
16 a probable, you know, carcinogenic to human.
17 So -- and another thing, you
18 know, I also wanted to, you know, point out,
19 you know, in terms of, you know, of these
20 like -- you know, like you mentioned, you
21 know, epidemiology, you know, studies, right,
22 these were all performed in early '90s, okay?
23 And as I also mentioned, you
24 know, yesterday, also maybe, you know, the

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1 day before, you know, we have more recent,
2 you know, you know, epidemiological, you
3 know, studies.
4 And in at least, you know, you
5 know, some of those studies, you know, the
6 conclusions, you know, are not consistent
7 with the conclusion showed up, you know, in
8 these early '90, you know, papers or studies.
9 MR. SLATER: Cheryll, let's
10 scroll down just so I can get the
11 bottom right-hand half of the page,
12 too. No, too far. Don't try to speed
13 us up here. A little more. Perfect.
14 Thank you.
15 BY MR. SLATER:
16 Q. Looking now at Section 11
17 that's titled "Effects Evaluation," and 11.1,
18 "Evaluation of health effects," and 11.1.1
19 says "Hazard identification."
20 Do you see that?
21 A. Yes, I do.
22 Q. In the hazard identification
23 section, that first paragraph, it says,
24 "Although NDMA is acutely toxic and induces

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1 hepatic damage in several species at dose
2 levels of approximately 1 mg/kg body weight
3 per day in short-term experiments, the main
4 concern is its carcinogenicity. NDMA has
5 been consistently shown to be a potent
6 carcinogen in all experimental species
7 studied."
8 Do you see that?
9 A. Yeah, experimental species,
10 yeah, means animals, yeah.
11 Q. You've mentioned animal studies
12 many times, and I think you made that point
13 multiple times. So why haven't there been
14 human studies done where humans have been
15 given NDMA to see what happens to humans?
16 A. That would be unethical.
17 Q. It would be unethical, right?
18 That's what you said?
19 A. Yes.
20 Q. Because --
21 A. Knowingly, yes, if you
22 knowingly do that, yes.
23 Q. It would be unethical because
24 you would know that you're likely -- well,

<p>Page 686</p> <p>1 rephrase.</p> <p>2 It would be unethical because</p> <p>3 you would be increasing the risk that these</p> <p>4 people would get cancer from having the NDMA</p> <p>5 put into their body, right?</p> <p>6 MR. GALLAGHER: Objection.</p> <p>7 Lacks foundation, and calls for expert</p> <p>8 testimony.</p> <p>9 A. As I think I already answered</p> <p>10 that question. It's just considering the</p> <p>11 potential risk. If you knowingly to do that</p> <p>12 experiment, it will be unethical.</p> <p>13 BY MR. SLATER:</p> <p>14 Q. It would be unethical to</p> <p>15 knowingly give humans NDMA, correct?</p> <p>16 MR. GALLAGHER: Objection.</p> <p>17 Calls for expert testimony.</p> <p>18 A. I think I already made that</p> <p>19 clear.</p> <p>20 BY MR. SLATER:</p> <p>21 Q. And it would certainly be</p> <p>22 unethical to give humans NDMA in the levels</p> <p>23 that were found in the valsartan pills</p> <p>24 deliberately and knowingly, correct?</p> <p>Page 687</p> <p>1 MR. GALLAGHER: Objection.</p> <p>2 Calls for expert testimony, and</p> <p>3 outside the scope.</p> <p>4 A. It's the same principle.</p> <p>5 BY MR. SLATER:</p> <p>6 Q. Looking now, if we can scroll</p> <p>7 down to 11.1.1.1, "Carcinogenicity" is the</p> <p>8 next section.</p> <p>9 Do you see that?</p> <p>10 A. Mm-hmm.</p> <p>11 MR. SLATER: Let's scroll now</p> <p>12 to the next page, please, the</p> <p>13 left-hand column, the first full</p> <p>14 paragraph. Let's get that up. That's</p> <p>15 just the carryover paragraph. Please</p> <p>16 go down a little further. That's</p> <p>17 perfect. Okay.</p> <p>18 Q. So -- rephrase.</p> <p>19 In the left-hand column, the</p> <p>20 first full paragraph, I want to start in the</p> <p>21 second sentence. It says, "The weight of</p> <p>22 evidence of the carcinogenicity of NDMA in</p> <p>23 mammalian species is consistent and</p> <p>24 convincing. Moreover, the pattern of tumor</p>	<p>Page 688</p> <p>1 development is characteristic of that for a</p> <p>2 mode of action of carcinogenesis involving</p> <p>3 direct interaction with genetic material. In</p> <p>4 available studies, NDMA has induced tumors in</p> <p>5 all species examined (mice, rats, hamsters),</p> <p>6 at relatively low doses in some cases,</p> <p>7 irrespective of the route of exposure,"</p> <p>8 whether oral or inhalation. "Tumors were</p> <p>9 induced in a wide range of tissues, including</p> <p>10 the liver, Leydig cells, lungs, kidney, and</p> <p>11 nasal cavity, in the absence of significant</p> <p>12 non-neoplastic effects, in the limited number</p> <p>13 of studies in which these were well</p> <p>14 examined."</p> <p>15 Do you see what I just read?</p> <p>16 A. Yes.</p> <p>17 Q. That language was not placed</p> <p>18 into the deviation investigation report that</p> <p>19 we were discussing a few moments ago,</p> <p>20 correct?</p> <p>21 A. As I indicate to you, you know,</p> <p>22 by reading through, you know, this whole</p> <p>23 sentence or whatever, it's still talking</p> <p>24 about, you know, its being a carcinogen to</p> <p>Page 689</p> <p>1 animals, okay, so we clearly made that</p> <p>2 statement in the deviation report.</p> <p>3 Q. My question is this. The</p> <p>4 language I just read is not set forth in the</p> <p>5 deviation investigation report, correct?</p> <p>6 A. The deviation report is not</p> <p>7 intended, you know, to go into such a, you</p> <p>8 know, extensive, you know, you know,</p> <p>9 discussion, okay. So it's basically state,</p> <p>10 you know, the fact, you know, that fact, you</p> <p>11 know, is consistent, you know, with</p> <p>12 everything, you know, this report or this</p> <p>13 particular paragraph, you know, states.</p> <p>14 Q. Let's continue.</p> <p>15 MR. SLATER: Can you scroll</p> <p>16 down a little more, Cheryll, just to</p> <p>17 capture the bottom of the paragraph?</p> <p>18 Q. The -- rephrase.</p> <p>19 This first full paragraph on</p> <p>20 page 23 of this study continues, "Where it</p> <p>21 was reported, time to first tumor was</p> <p>22 relatively short. The incidence of specific</p> <p>23 tumors has been increased following</p> <p>24 administration of even a single dose or</p>
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1 repeated doses for short periods (i.e. 2-3
 2 weeks); tumors have also been observed in the
 3 offspring of exposed pregnant rats and mice."
 4 Do you see that?
 5 A. I'm sorry, which -- which
 6 paragraph?
 7 Q. It's the same paragraph we were
 8 just reading in --
 9 A. Oh, okay, okay, okay, sure.
 10 Uh-huh, uh-huh.
 11 Q. What I just read, along with
 12 the other things that I read above that, goes
 13 to the concept of this being a potent
 14 mutagenic carcinogen, correct?
 15 MR. GALLAGHER: Objection.
 16 Vague, calls for expert testimony.
 17 A. Again, you know, everything is
 18 talk about here is still, you know, related
 19 to animals.
 20 MR. SLATER: Cheryll, could you
 21 scroll down so we capture the last two
 22 paragraphs in that column, please?
 23 Perfect.
 24 Q. This article continues on

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1 page 23, the last two paragraph -- rephrase.
 2 Continue on page 23 of the
 3 article, the second to last paragraph in the
 4 left column says, "NDMA has been consistently
 5 mutagenic and clastogenic in human and rodent
 6 cells exposed to in vitro. Clear evidence of
 7 genetic effects has also been observed in a
 8 number of tissues from animals exposed to
 9 this substance. Notably, genotoxic effects
 10 have been observed in tissues (i.e., liver,
 11 kidney, lung) where tumors commonly arise
 12 following experimental exposure to NDMA and
 13 in germ cells."
 14 Do you see that?
 15 A. Yes.
 16 Q. This continues now in the last
 17 paragraph in the left column, "DNA adducts
 18 (in particular, O6-methylguanine) formed by
 19 the methyl diazonium ion generated during
 20 metabolism likely play a critical role in
 21 NDMA carcinogenicity. Observed variations in
 22 carcinogenicity among species and strains
 23 correlate well with variations in activity of
 24 O6-methylguanine DNA-methyltransferase.

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1 Putative pathways for the metabolism of NDMA
 2 are similar in rodents and humans, and indeed
 3 the formation of O6-methylguanine has been
 4 detected in human tissues exposed to NDMA."
 5 You see what I just read, I
 6 assume, correct?
 7 A. Yes.
 8 Q. So in this article which your
 9 company cited in its deviation investigation
 10 report, they're essentially building the case
 11 for the similarities between humans and
 12 animals that are significant in determining
 13 whether NDMA causes cancer in humans; that's
 14 basically what they're discussing and
 15 building to here, correct?
 16 A. As I said, you know --
 17 MR. GALLAGHER: Objection,
 18 vague. Objection. Vague, calls for
 19 expert testimony, and to the extent it
 20 mischaracterizes the document.
 21 A. Again, you know, it -- as I
 22 said, everything, you know, presented here,
 23 you know, it -- it's only, you know,
 24 indicate, you know, it's a -- it's a

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1 carcinogenic to animals and it's a probable
 2 carcinogenic to humans.
 3 BY MR. SLATER:
 4 Q. Let's go up -- well, let me ask
 5 you this question before we scroll any
 6 further.
 7 In terms of what's likely, at
 8 the levels that we've gone through in this
 9 deposition, there are some people who took
 10 the valsartan sold by ZHP that was
 11 contaminated with NDMA who will or already
 12 have developed cancer at least in part
 13 because of their exposure to that NDMA,
 14 correct?
 15 MR. GALLAGHER: Objection.
 16 Vague, lacks foundation, calls for
 17 speculation, and calls for expert
 18 testimony.
 19 A. This is way beyond, okay, my
 20 scope, okay. It need to be examined, or it
 21 need to be evaluated by medical doctors or,
 22 as I said, or as well as toxicologists.
 23 BY MR. SLATER:
 24 Q. Knowing the science available

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1 to ZHP, it is certainly more likely than not
 2 that at the levels of NDMA seen in the
 3 valsartan sold by ZHP, there are some people
 4 who took that who will likely or already have
 5 likely developed cancer at least in part due
 6 to that exposure to NDMA.
 7 We don't have to argue about
 8 how many people, we don't have to argue about
 9 which cancers. But you can agree that that's
 10 happened to some people, or will, correct?
 11 MR. GALLAGHER: Objection.
 12 Vague, lacks foundation, calls for
 13 speculation, calls for expert
 14 testimony, outside the scope, and
 15 argumentative.
 16 A. That's your -- yeah, basically,
 17 again, that's your speculation, okay. As far
 18 as I know, this is not a fact, okay, as, you
 19 know, until -- you know, up to this point.
 20 Okay. That's your speculation.
 21 BY MR. SLATER:
 22 Q. Well, it's certainly likely
 23 that that will happen or has happened to some
 24 people, correct?

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1 MR. GALLAGHER: Objection.
 2 Vague, lacks foundation, calls for
 3 speculation, calls for expert
 4 testimony, outside the scope, and
 5 argumentative.
 6 A. You know, as I said, I have
 7 responded multiple times. That's your
 8 speculation.
 9 BY MR. SLATER:
 10 Q. You would certainly agree with
 11 me that the people who took the valsartan
 12 manufactured by ZHP and contaminated with
 13 NDMA have an increased risk as a result of
 14 that exposure to develop cancer.
 15 You'll agree with that, right?
 16 MR. GALLAGHER: Objection.
 17 Vague, lacks foundation, calls for
 18 speculation, calls for expert
 19 testimony, outside the scope, and
 20 argumentative.
 21 A. You know, you want me to repeat
 22 still the same answer. You know, you are
 23 making a speculation.
 24 MR. SLATER: Let's look at the

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1 article, the top right-hand column of
 2 this page, page 23.
 3 Q. Looking again at this article
 4 cited by ZHP and relied on by ZHP in its
 5 deviation investigation report, the top right
 6 column on page 23 -- do you see where I am?
 7 A. The top right, the first
 8 paragraph?
 9 Q. Yes.
 10 A. Okay, yeah, I see that.
 11 Q. It says, "Therefore, owing to
 12 the considerable evidence of carcinogenicity
 13 of NDMA in laboratory species, evidence of
 14 direct interaction with DNA consistent with
 15 tumour formation, and the apparent lack of
 16 qualitative species-specific differences in
 17 the metabolism of this substance, NDMA is
 18 highly likely to be carcinogenic to humans."
 19 That's what this article
 20 states, correct?
 21 A. Yeah. Based upon, you know,
 22 the last sentence, you know, you know,
 23 another way to say is NDMA, you know, is a
 24 probable, you know, carcinogen to human.

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1 It's still the same thing.
 2 Q. Yeah. Probable, yeah.
 3 A. Highly likely, you know, is
 4 probable.
 5 So that's why, you know, as I
 6 said, IARC, you know, even as of today, you
 7 know, after what, like more than 20 years,
 8 you know, you know, after the publishing of
 9 this article, you know, it's still the same
 10 characterization as 2A, you know, Class 2A.
 11 Q. "Highly likely to be
 12 carcinogenic to humans" means that it --
 13 rephrase.
 14 "Highly likely to be
 15 carcinogenic to humans" means exposure to
 16 NDMA will cause cancer in humans, correct?
 17 MR. GALLAGHER: Objection.
 18 Vague, calls for speculation, and lack
 19 of foundation, and outside the scope.
 20 A. See, again, you know, you just
 21 try to twist, you know, you know, the fact.
 22 Okay. You try to twist "highly likely" or,
 23 you know, you know, "probable." You know,
 24 you try to equating them to certainty, okay.

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1 That's just not the case.
2 BY MR. SLATER:
3 Q. In medicine and in science,
4 there's a reasonable degree of probability.
5 You know that concept, right?
6 MR. GALLAGHER: Objection.
7 Vague, calls for expert testimony, and
8 outside the scope.
9 Dr. Li, to the extent you know.
10 A. To the extent -- yeah, there's
11 a possibility, yeah.
12 BY MR. SLATER:
13 Q. I asked you a different
14 question.
15 You understand the concept of
16 reasonable degree of scientific probability
17 or scientific -- rephrase.
18 Do you understand the concept
19 of reasonable degree of scientific certainty?
20 MR. GALLAGHER: Objection.
21 Vague.
22 A. Yeah. So I don't know what
23 you're specifically try to, you know, to say
24 or to, you know, referring to.

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1 BY MR. SLATER:
2 Q. Well, I'll ask the question
3 differently.
4 NDMA is highly likely to be
5 carcinogenic to humans. That's why your
6 company had to stop selling valsartan
7 contaminated with NDMA, correct?
8 MR. GALLAGHER: Objection.
9 Vague, lacks foundation, and outside
10 the scope.
11 A. As I responded earlier, as I
12 said, you know, to stop distribution, you
13 know, as a responsible company it's -- you
14 know, once, you know, the company, you know,
15 became to know, and also, you know, after we
16 developed the method, right, and we know the
17 range, then we immediately, you know, you
18 know, contact FDA. You know, so that
19 decision, you know, was based upon, you know,
20 this potential risk. Okay?
21 BY MR. SLATER:
22 Q. Your company stopped selling --
23 well, let me ask it this way.
24 At the levels of contamination

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1 that we've gone through in this deposition,
2 it would be unacceptable and, using your
3 word, unethical to sell valsartan with those
4 levels of NDMA contamination, correct?
5 MR. GALLAGHER: Objection.
6 Vague, mischaracterizes testimony,
7 calls for speculation, calls for
8 expert testimony, and outside the
9 scope.
10 A. You know, as I said, you know,
11 if you knowingly do that, okay.
12 BY MR. SLATER:
13 Q. I'm sorry, what did you say?
14 A. As I said before, you know, if
15 you knowingly doing that.
16 MR. SLATER: Thank you.
17 Patrick, I don't know if you
18 have any questions. I can reserve the
19 rest of my time, or we can conclude
20 the deposition now.
21 MR. GALLAGHER: I'm happy to
22 conclude the deposition.
23 MR. SLATER: Thank you very
24 much. I'm done.

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1 MR. GALLAGHER: Thank you.
2 THE VIDEOGRAPHER: The time
3 right now is 11:17 a.m. We're now off
4 the record.
5 (Whereupon, the deposition was
6 concluded.)
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